

106TH CONGRESS
1ST SESSION

H. R. 2926

To provide new patient protections under group health plans and through health insurance issuers in the group market.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1999

Mr. BOEHNER (for himself, Mr. ARMEY, Mr. BLILEY, Mr. GOODLING, Mrs. NORTHUP, Mr. MCCRERY, Mr. GREEN of Wisconsin, Mr. TALENT, Mr. OXLEY, Mr. PORTMAN, Mr. HOBSON, Mr. BALLENGER, and Mr. SALMON) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, Ways and Means, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide new patient protections under group health plans and through health insurance issuers in the group market.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Access and Responsibility in Health Care
6 Act of 1999”.

- 1 (b) TABLE OF CONTENTS.—The table of contents is
 2 as follows:

Sec. 1. Short title and table of contents.

TITLE I—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Subtitle A—Patient Protections

- Sec. 101. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.
 Sec. 102. Required disclosure to network providers.
 Sec. 103. Effective date and related rules.

Subtitle B—Patient Access to Information

- Sec. 111. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.
 Sec. 112. Effective date and related rules.

Subtitle C—Group Health Plan Review Standards

- Sec. 121. Special rules for group health plans.
 Sec. 122. Special rule for access to specialty care.
 Sec. 123. Requirements for treatment of prescription drugs and medical devices as experimental or investigational.
 Sec. 124. Protection for certain information developed to reduce mortality or morbidity or for improving patient care and safety.
 Sec. 125. Effective date.

Subtitle D—Small Business Access and Choice for Entrepreneurs

- Sec. 131. Rules governing association health plans.

“PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

- “Sec. 801. Association health plans.
 “Sec. 802. Certification of association health plans.
 “Sec. 803. Requirements relating to sponsors and boards of trustees.
 “Sec. 804. Participation and coverage requirements.
 “Sec. 805. Other requirements relating to plan documents, contribution rates, and benefit options.
 “Sec. 806. Maintenance of reserves and provisions for solvency for plans providing health benefits in addition to health insurance coverage.
 “Sec. 807. Requirements for application and related requirements.
 “Sec. 808. Notice requirements for voluntary termination.
 “Sec. 809. Corrective actions and mandatory termination.
 “Sec. 810. Trusteeship by the secretary of insolvent association health plans providing health benefits in addition to health insurance coverage.
 “Sec. 811. State assessment authority.
 “Sec. 812. Definitions and rules of construction.
 Sec. 132. Clarification of treatment of single employer arrangements.

- Sec. 133. Clarification of treatment of certain collectively bargained arrangements.
- Sec. 134. Enforcement provisions relating to association health plans.
- Sec. 135. Cooperation between Federal and State authorities.
- Sec. 136. Effective date and transitional and other rules.

Subtitle E—Health Care Access, Affordability, and Quality Commission

- Sec. 141. Establishment of commission.
- Sec. 142. Effective date.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Subtitle A—Patient Protections and Point of Service Coverage Requirements

- Sec. 201. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.
- Sec. 202. Requiring health maintenance organizations to offer option of point-of-service coverage.
- Sec. 203. Effective date and related rules.

Subtitle B—Patient Access to Information

- Sec. 211. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.
- Sec. 212. Requirements for treatment of prescription drugs and medical devices as experimental or investigational.
- Sec. 213. Effective date and related rules.

Subtitle C—HealthMarts

- Sec. 221. Expansion of consumer choice through HealthMarts.
- Sec. 222. Effective date.

Subtitle D—Community Health Organizations

- Sec. 231. Promotion of provision of insurance by community health organizations.

TITLE III—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subtitle A—Patient Protections

- Sec. 301. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

Subtitle B—Medical Savings Accounts

- Sec. 311. Expansion of availability of medical savings accounts.
- Sec. 312. Effective date.

Subtitle C—Tax Incentives for Health Care

- Sec. 321. Deduction for health and long-term care insurance costs of individuals not participating in employer-subsidized health plans.
- Sec. 322. Refundable credit for health insurance coverage.

- Sec. 323. Study of State safety-net health insurance programs for the medically uninsurable.
- Sec. 324. Carryover of unused benefits from cafeteria plans and flexible spending arrangements.

TITLE IV—HEALTH CARE LAWSUIT REFORM

Subtitle A—General Provisions

- Sec. 401. Federal reform of health care liability actions.
- Sec. 402. Definitions.
- Sec. 403. Effective date.

Subtitle B—Uniform Standards for Health Care Liability Actions

- Sec. 411. Statute of limitations.
- Sec. 412. Calculation and payment of damages.
- Sec. 413. Limitations on contingent fees.
- Sec. 413. Alternative dispute resolution.
- Sec. 414. Reporting on fraud and abuse enforcement activities.

1 **TITLE I—AMENDMENTS TO THE**

2 **EMPLOYEE RETIREMENT IN-**

3 **COME SECURITY ACT OF 1974**

4 **Subtitle A—Patient Protections**

5 **SEC. 101. PATIENT ACCESS TO UNRESTRICTED MEDICAL**

6 **ADVICE, EMERGENCY MEDICAL CARE, OB-**

7 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**

8 **ATRIC CARE, AND CONTINUITY OF CARE.**

9 (a) IN GENERAL.—Subpart B of part 7 of subtitle

10 B of title I of the Employee Retirement Income Security

11 Act of 1974 is amended by adding at the end the following

12 new section:

1 **"SEC. 714. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
2 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
3 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
4 **ATRIC CARE, AND CONTINUITY OF CARE.**

5 **"(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
6 **ADVICE.—**

7 **"(1) IN GENERAL.—**In the case of any health
8 care professional acting within the lawful scope of
9 practice in the course of carrying out a contractual
10 employment arrangement or other direct contractual
11 arrangement between such professional and a group
12 health plan or a health insurance issuer offering
13 health insurance coverage in connection with a group
14 health plan, the plan or issuer with which such con-
15 tractual employment arrangement or other direct
16 contractual arrangement is maintained by the pro-
17 fessional may not impose on such professional under
18 such arrangement any prohibition or restriction with
19 respect to advice, provided to a participant or bene-
20 ficiary under the plan who is a patient, about the
21 health status of the participant or beneficiary or the
22 medical care or treatment for the condition or dis-
23 ease of the participant or beneficiary, regardless of
24 whether benefits for such care or treatment are pro-
25 vided under the plan or health insurance coverage
26 offered in connection with the plan.

1 “(2) HEALTH CARE PROFESSIONAL DEFINED.—

2 For purposes of this paragraph, the term ‘health
3 care professional’ means a physician (as defined in
4 section 1861(r) of the Social Security Act) or other
5 health care professional if coverage for the profes-
6 sional’s services is provided under the group health
7 plan for the services of the professional. Such term
8 includes a podiatrist, optometrist, chiropractor, psy-
9 chologist, dentist, physician assistant, physical or oc-
10 cupational therapist and therapy assistant, speech-
11 language pathologist, audiologist, registered or li-
12 censed practical nurse (including nurse practitioner,
13 clinical nurse specialist, certified registered nurse
14 anesthetist, and certified nurse-midwife), licensed
15 certified social worker, registered respiratory thera-
16 pist, and certified respiratory therapy technician.

17 “(3) RULE OF CONSTRUCTION.—Nothing in
18 this subsection shall be construed to require the
19 sponsor of a group health plan or a health insurance
20 issuer offering health insurance coverage in connec-
21 tion with the group health plan to engage in any
22 practice that would violate its religious beliefs or
23 moral convictions.

24 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
25 CARE.—

1 “(1) COVERAGE OF EMERGENCY SERVICES.—

2 “(A) IN GENERAL.—If a group health
3 plan, or health insurance coverage offered by a
4 health insurance issuer, provides any benefits
5 with respect to emergency services (as defined
6 in subparagraph (B)(ii)), or ambulance services,
7 the plan or issuer shall cover emergency serv-
8 ices (including emergency ambulance services as
9 defined in subparagraph (B)(iii)) furnished
10 under the plan or coverage—

11 “(i) without the need for any prior
12 authorization determination;

13 “(ii) whether or not the health care
14 provider furnishing such services is a par-
15 ticipating provider with respect to such
16 services;

17 “(iii) in a manner so that, if such
18 services are provided to a participant or
19 beneficiary by a nonparticipating health
20 care provider, the participant or bene-
21 ficiary is not liable for amounts that ex-
22 ceed the amounts of liability that would be
23 incurred if the services were provided by a
24 participating provider; and

1 “(iv) without regard to any other term
2 or condition of such plan or coverage
3 (other than exclusion or coordination of
4 benefits, or an affiliation or waiting period,
5 permitted under section 701 and other
6 than applicable cost sharing).

7 “(B) DEFINITIONS.—In this subsection:

8 “(i) EMERGENCY MEDICAL CONDI-
9 TION.—The term ‘emergency medical con-
10 dition’ means—

11 “(I) a medical condition mani-
12 festing itself by acute symptoms of
13 sufficient severity (including severe
14 pain) such that a prudent layperson,
15 who possesses an average knowledge
16 of health and medicine, could reason-
17 ably expect the absence of immediate
18 medical attention to result in a condi-
19 tion described in clause (i), (ii), or
20 (iii) of section 1867(e)(1)(A) of the
21 Social Security Act (42 U.S.C.
22 1395dd(e)(1)(A)); and

23 “(II) a medical condition mani-
24 festing itself in a neonate by acute
25 symptoms of sufficient severity (in-

cluding severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(ii) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd)) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in clause (i)) and also, within the capabilities of the staff and facilities at the hospital, such further medical examination and treatment as are

1 required under section 1867 of such
2 Act to stabilize the patient; or

3 “(II) with respect to an emer-
4 gency medical condition described in
5 clause (i)(II), medical treatment for
6 such condition rendered by a health
7 care provider in a hospital to a
8 neonate, including available hospital
9 ancillary services in response to an ur-
10 gent request of a health care profes-
11 sional and to the extent necessary to
12 stabilize the neonate.

13 “(iii) EMERGENCY AMBULANCE SERV-
14 ICES.—The term ‘emergency ambulance
15 services’ means ambulance services (as de-
16 fined for purposes of section 1861(s)(7) of
17 the Social Security Act) furnished to trans-
18 port an individual who has an emergency
19 medical condition (as defined in clause (i))
20 to a hospital for the receipt of emergency
21 services (as defined in clause (ii)) in a case
22 in which appropriate emergency medical
23 screening examinations are covered under
24 the plan or coverage pursuant to para-
25 graph (1)(A) and a prudent layperson,

1 with an average knowledge of health and
2 medicine, could reasonably expect that the
3 absence of such transport would result in
4 placing the health of the individual in seri-
5 ous jeopardy, serious impairment of bodily
6 function, or serious dysfunction of any
7 bodily organ or part.

8 “(iv) STABILIZE.—The term ‘to sta-
9 bilize’ means, with respect to an emergency
10 medical condition, to provide such medical
11 treatment of the condition as may be nec-
12 essary to assure, within reasonable medical
13 probability, that no material deterioration
14 of the condition is likely to result from or
15 occur during the transfer of the individual
16 from a facility.

17 “(v) NONPARTICIPATING.—The term
18 ‘nonparticipating’ means, with respect to a
19 health care provider that provides health
20 care items and services to a participant or
21 beneficiary under group health plan or
22 under group health insurance coverage, a
23 health care provider that is not a partici-
24 pating health care provider with respect to
25 such items and services.

1 “(vi) PARTICIPATING.—The term
 2 ‘participating’ means, with respect to a
 3 health care provider that provides health
 4 care items and services to a participant or
 5 beneficiary under group health plan or
 6 health insurance coverage offered by a
 7 health insurance issuer in connection with
 8 such a plan, a health care provider that
 9 furnishes such items and services under a
 10 contract or other arrangement with the
 11 plan or issuer.

12 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
 13 LOGICAL CARE.—

14 “(1) IN GENERAL.—In any case in which a
 15 group health plan (or a health insurance issuer of-
 16 fering health insurance coverage in connection with
 17 the plan)—

18 “(A) provides benefits under the terms of
 19 the plan consisting of—

20 “(i) gynecological care (such as pre-
 21 ventive women’s health examinations); or

22 “(ii) obstetric care (such as preg-
 23 nancy-related services),

24 provided by a participating health care profes-
 25 sional who specializes in such care (or provides

benefits consisting of payment for such care);
and

“(B) requires or provides for designation
by a participant or beneficiary of a participating primary care provider,

if the primary care provider designated by such a participant or beneficiary is not such a health care professional, then the plan (or issuer) shall meet the requirements of paragraph (2).

“(2) REQUIREMENTS.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) meets the requirements of this paragraph, in connection with benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan (or issuer)—

“(A) does not require authorization or a referral by the primary care provider in order to obtain such benefits; and

“(B) treats the ordering of other care of the same type, by the participating health care professional providing the care described in clause (i) or (ii) of paragraph (1)(A), as the au-

1 thorization of the primary care provider with
2 respect to such care.

3 “(3) HEALTH CARE PROFESSIONAL DEFINED.—

4 For purposes of this subsection, the term ‘health
5 care professional’ means an individual (including,
6 but not limited to, a nurse midwife or nurse practi-
7 tioner) who is licensed, accredited, or certified under
8 State law to provide obstetric and gynecological
9 health care services and who is operating within the
10 scope of such licensure, accreditation, or certifi-
11 cation.

12 “(4) CONSTRUCTION.—Nothing in paragraph
13 (1) shall be construed as preventing a plan from of-
14 fering (but not requiring a participant or beneficiary
15 to accept) a health care professional trained,
16 credentialed, and operating within the scope of their
17 licensure to perform obstetric and gynecological
18 health care services. Nothing in paragraph (2)(B)
19 shall waive any requirements of coverage relating to
20 medical necessity or appropriateness with respect to
21 coverage of gynecological or obstetric care so or-
22 dered.

23 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
24 TIONS.—In the case of a plan providing benefits
25 under two or more coverage options, the require-

ments of this subsection shall apply separately with respect to each coverage option.

“(d) PATIENT RIGHT TO PEDIATRIC CARE.—

“(1) IN GENERAL.—In any case in which a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides benefits consisting of routine pediatric care provided by a participating health care professional who specializes in pediatrics (or consisting of payment for such care) and the plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, the plan (or issuer) shall provide that such a participating health care professional may be designated, if available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—

For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse practitioner) who is licensed, accredited, or certified under State law to provide pediatric health care services and who is op-

1 erating within the scope of such licensure, accredita-
2 tion, or certification.

3 “(3) CONSTRUCTION.—Nothing in paragraph
4 (1) shall be construed as preventing a plan from of-
5 fering (but not requiring a participant or beneficiary
6 to accept) a health care professional trained,
7 credentialed, and operating within the scope of their
8 licensure to perform pediatric health care services.
9 Nothing in paragraph (1) shall waive any require-
10 ments of coverage relating to medical necessity or
11 appropriateness with respect to coverage of pediatric
12 care so ordered.

13 “(4) TREATMENT OF MULTIPLE COVERAGE OP-
14 TIONS.—In the case of a plan providing benefits
15 under two or more coverage options, the require-
16 ments of this subsection shall apply separately with
17 respect to each coverage option.

18 “(e) CONTINUITY OF CARE.—

19 “(1) IN GENERAL.—

20 “(A) TERMINATION OF PROVIDER.—If a
21 contract between a group health plan, or a
22 health insurance issuer offering health insur-
23 ance coverage in connection with a group health
24 plan, and a health care provider is terminated
25 (as defined in subparagraph (D)(ii)), or benefits

1 or coverage provided by a health care provider
2 are terminated because of a change in the
3 terms of provider participation in a group
4 health plan, and an individual who, at the time
5 of such termination, is a participant or bene-
6 ficiary in the plan and is scheduled to undergo
7 surgery (including an organ transplantation), is
8 undergoing treatment for pregnancy, or is de-
9 termined to be terminally ill (as defined in sec-
10 tion 1861(dd)(3)(A) of the Social Security Act)
11 and is undergoing treatment for the terminal
12 illness, the plan or issuer shall—

13 “(i) notify the individual on a timely
14 basis of such termination and of the right
15 to elect continuation of coverage of treat-
16 ment by the provider under this sub-
17 section; and

18 “(ii) subject to paragraph (3), permit
19 the individual to elect to continue to be
20 covered with respect to treatment by the
21 provider for such surgery, pregnancy, or
22 illness during a transitional period (pro-
23 vided under paragraph (2)).

24 “(B) TREATMENT OF TERMINATION OF
25 CONTRACT WITH HEALTH INSURANCE

1 ISSUER.—If a contract for the provision of
2 health insurance coverage between a group
3 health plan and a health insurance issuer is ter-
4 minated and, as a result of such termination,
5 coverage of services of a health care provider
6 is terminated with respect to an individual, the
7 provisions of subparagraph (A) (and the suc-
8 ceeding provisions of this subsection) shall
9 apply under the plan in the same manner as
10 if there had been a contract between the plan
11 and the provider that had been terminated, but
12 only with respect to benefits that are covered
13 under the plan after the contract termination.

14 “(C) TERMINATION DEFINED.—For pur-
15 poses of this subsection, the term ‘terminated’
16 includes, with respect to a contract, the expira-
17 tion or nonrenewal of the contract, but does not
18 include a termination of the contract by the
19 plan or issuer for failure to meet applicable
20 quality standards or for fraud.

21 “(2) TRANSITIONAL PERIOD.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraphs (B) through (D), the transi-
24 tional period under this paragraph shall extend
25 up to 90 days (as determined by the treating

1 health care professional) after the date of the
2 notice described in paragraph (1)(A)(i) of the
3 provider's termination.

4 “(B) SCHEDULED SURGERY.—If surgery
5 was scheduled for an individual before the date
6 of the announcement of the termination of the
7 provider status under paragraph (1)(A)(i), the
8 transitional period under this paragraph with
9 respect to the surgery shall extend beyond the
10 period under subparagraph (A) and until the
11 date of discharge of the individual after comple-
12 tion of the surgery.

13 “(C) PREGNANCY.—If—

14 “(i) a participant or beneficiary was
15 determined to be pregnant at the time of
16 a provider's termination of participation,
17 and

18 “(ii) the provider was treating the
19 pregnancy before date of the termination,
20 the transitional period under this paragraph
21 with respect to provider's treatment of the
22 pregnancy shall extend through the provision of
23 post-partum care directly related to the deliv-
24 ery.

25 “(D) TERMINAL ILLNESS.—If—

1 “(i) a participant or beneficiary was
2 determined to be terminally ill (as deter-
3 mined under section 1861(dd)(3)(A) of the
4 Social Security Act) at the time of a pro-
5 vider’s termination of participation, and

6 “(ii) the provider was treating the ter-
7 minal illness before the date of termi-
8 nation,

9 the transitional period under this paragraph
10 shall extend for the remainder of the individ-
11 ual’s life for care directly related to the treat-
12 ment of the terminal illness or its medical
13 manifestations.

14 “(3) PERMISSIBLE TERMS AND CONDITIONS.—
15 A group health plan or health insurance issuer may
16 condition coverage of continued treatment by a pro-
17 vider under paragraph (1)(A)(i) upon the individual
18 notifying the plan of the election of continued cov-
19 erage and upon the provider agreeing to the fol-
20 lowing terms and conditions:

21 “(A) The provider agrees to accept reim-
22 bursement from the plan or issuer and indi-
23 vidual involved (with respect to cost-sharing) at
24 the rates applicable prior to the start of the
25 transitional period as payment in full (or, in the

1 case described in paragraph (1)(B), at the rates
2 applicable under the replacement plan or issuer
3 after the date of the termination of the contract
4 with the health insurance issuer) and not to im-
5 pose cost-sharing with respect to the individual
6 in an amount that would exceed the cost-shar-
7 ing that could have been imposed if the contract
8 referred to in paragraph (1)(A) had not been
9 terminated.

10 “(B) The provider agrees to adhere to the
11 quality assurance standards of the plan or
12 issuer responsible for payment under subpara-
13 graph (A) and to provide to such plan or issuer
14 necessary medical information related to the
15 care provided.

16 “(C) The provider agrees otherwise to ad-
17 here to such plan’s or issuer’s policies and pro-
18 cedures, including procedures regarding refer-
19 rals and obtaining prior authorization and pro-
20 viding services pursuant to a treatment plan (if
21 any) approved by the plan or issuer.

22 “(D) The provider agrees to provide tran-
23 sitional care to all participants and beneficiaries
24 who are eligible for and elect to have coverage
25 of such care from such provider.

1 “(E) If the provider initiates the termi-
2 nation, the provider has notified the plan within
3 30 days prior to the effective date of the termi-
4 nation of—

5 “(i) whether the provider agrees to
6 permissible terms and conditions (as set
7 forth in this paragraph) required by the
8 plan, and

9 “(ii) if the provider agrees to the
10 terms and conditions, the specific plan
11 beneficiaries and participants undergoing a
12 course of treatment from the provider who
13 the provider believes, at the time of the no-
14 tification, would be eligible for transitional
15 care under this subsection.

16 “(4) CONSTRUCTION.—Nothing in this sub-
17 section shall be construed to—

18 “(A) require the coverage of benefits which
19 would not have been covered if the provider in-
20 volved remained a participating provider, or

21 “(B) prohibit a group health plan from
22 conditioning a provider’s participation on the
23 provider’s agreement to provide transitional
24 care to all participants and beneficiaries eligible

1 to obtain coverage of such care furnished by the
2 provider as set forth under this subsection.

3 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
4 APPROVED CANCER CLINICAL TRIALS.—

5 “(1) COVERAGE.—

6 “(A) IN GENERAL.—If a group health plan
7 (or a health insurance issuer offering health in-
8 surance coverage in connection with the plan)
9 provides coverage to a qualified individual (as
10 defined in paragraph (2)), the plan or issuer—

11 “(i) may not deny the individual par-
12 ticipation in the clinical trial referred to in
13 paragraph (2)(B);

14 “(ii) subject to paragraphs (2), (3),
15 and (4), may not deny (or limit or impose
16 additional conditions on) the coverage of
17 routine patient costs for items and services
18 furnished in connection with participation
19 in the trial; and

20 “(iii) may not discriminate against the
21 individual on the basis of the participation
22 of the participant or beneficiary in such
23 trial.

24 “(B) EXCLUSION OF CERTAIN COSTS.—

25 For purposes of subparagraph (A)(ii), routine

1 patient costs do not include the cost of the tests
2 or measurements conducted primarily for the
3 purpose of the clinical trial involved.

4 “(C) USE OF IN-NETWORK PROVIDERS.—If
5 one or more participating providers is partici-
6 pating in a clinical trial, nothing in subpara-
7 graph (A) shall be construed as preventing a
8 plan from requiring that a qualified individual
9 participate in the trial through such a partici-
10 pating provider if the provider will accept the
11 individual as a participant in the trial.

12 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
13 purposes of paragraph (1), the term ‘qualified indi-
14 vidual’ means an individual who is a participant or
15 beneficiary in a group health plan and who meets
16 the following conditions:

17 “(A)(i) The individual has been diagnosed
18 with cancer.

19 “(ii) The individual is eligible to partici-
20 pate in an approved clinical trial according to
21 the trial protocol with respect to treatment of
22 cancer.

23 “(iii) The individual’s participation in the
24 trial offers meaningful potential for significant
25 clinical benefit for the individual.

1 “(B) Either—

2 “(i) the referring physician is a par-
3 ticipating health care professional and has
4 concluded that the individual’s participa-
5 tion in such trial would be appropriate
6 based upon satisfaction by the individual of
7 the conditions described in subparagraph
8 (A); or

9 “(ii) the individual provides medical
10 and scientific information establishing that
11 the individual’s participation in such trial
12 would be appropriate based upon the satis-
13 faction by the individual of the conditions
14 described in subparagraph (A).

15 “(3) PAYMENT.—

16 “(A) IN GENERAL.—A group health plan
17 (or a health insurance issuer offering health in-
18 surance coverage in connection with the plan)
19 shall provide for payment for routine patient
20 costs described in paragraph (1)(B) but is not
21 required to pay for costs of items and services
22 that are reasonably expected to be paid for by
23 the sponsors of an approved clinical trial.

24 “(B) ROUTINE PATIENT CARE COSTS.—

1 “(i) IN GENERAL.—For purposes of
2 this paragraph, the term ‘routine patient
3 care costs’ shall include the costs associ-
4 ated with the provision of items and serv-
5 ices that—

6 “(I) would otherwise be covered
7 under the group health plan if such
8 items and services were not provided
9 in connection with an approved clin-
10 ical trial program; and

11 “(II) are furnished according to
12 the protocol of an approved clinical
13 trial program.

14 “(ii) EXCLUSION.—For purposes of
15 this paragraph, ‘routine patient care costs’
16 shall not include the costs associated with
17 the provision of—

18 “(I) an investigational drug or
19 device, unless the Secretary has au-
20 thorized the manufacturer of such
21 drug or device to charge for such drug
22 or device; or

23 “(II) any item or service supplied
24 without charge by the sponsor of the
25 approved clinical trial program.

1 “(C) PAYMENT RATE.—For purposes of
2 this subsection—

3 “(i) PARTICIPATING PROVIDERS.—In
4 the case of covered items and services pro-
5 vided by a participating provider, the pay-
6 ment rate shall be at the agreed upon rate.

7 “(ii) NONPARTICIPATING PRO-
8 VIDERS.—In the case of covered items and
9 services provided by a nonparticipating
10 provider, the payment rate shall be at the
11 rate the plan would normally pay for com-
12 parable items or services under clause (i).

13 “(4) APPROVED CLINICAL TRIAL DEFINED.—

14 “(A) IN GENERAL.—For purposes of this
15 subsection, the term ‘approved clinical trial’
16 means a cancer clinical research study or can-
17 cer clinical investigation approved by an Institu-
18 tional Review Board.

19 “(B) CONDITIONS FOR DEPARTMENTS.—
20 The conditions described in this paragraph, for
21 a study or investigation conducted by a Depart-
22 ment, are that the study or investigation has
23 been reviewed and approved through a system
24 of peer review that the Secretary determines—

1 “(i) to be comparable to the system of
2 peer review of studies and investigations
3 used by the National Institutes of Health,
4 and

5 “(ii) assures unbiased review of the
6 highest scientific standards by qualified in-
7 dividuals who have no interest in the out-
8 come of the review.

9 “(5) CONSTRUCTION.—Nothing in this sub-
10 section shall be construed to limit a plan’s coverage
11 with respect to clinical trials.

12 “(6) PLAN SATISFACTION OF CERTAIN RE-
13 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

14 “(A) IN GENERAL.—For purposes of this
15 subsection, insofar as a group health plan pro-
16 vides benefits in the form of health insurance
17 coverage through a health insurance issuer, the
18 plan shall be treated as meeting the require-
19 ments of this subsection with respect to such
20 benefits and not be considered as failing to
21 meet such requirements because of a failure of
22 the issuer to meet such requirements so long as
23 the plan sponsor or its representatives did not
24 cause such failure by the issuer.

1 “(B) CONSTRUCTION.—Nothing in this
2 subsection shall be construed to affect or mod-
3 ify the responsibilities of the fiduciaries of a
4 group health plan under part 4.

5 “(7) STUDY AND REPORT.—

6 “(A) STUDY.—The Secretary shall analyze
7 cancer clinical research and its cost implications
8 for managed care, including differentiation in—

9 “(i) the cost of patient care in trials
10 versus standard care;

11 “(ii) the cost effectiveness achieved in
12 different sites of service;

13 “(iii) research outcomes;

14 “(iv) volume of research subjects
15 available in different sites of service;

16 “(v) access to research sites and clin-
17 ical trials by cancer patients;

18 “(vi) patient cost sharing or copay-
19 ment costs realized in different sites of
20 service;

21 “(vii) health outcomes experienced in
22 different sites of service;

23 “(viii) long term health care services
24 and costs experienced in different sites of
25 service;

1 “(ix) morbidity and mortality experi-
2 enced in different sites of service; and

3 “(x) patient satisfaction and pref-
4 erence of sites of service.

5 “(B) REPORT TO CONGRESS.—Not later
6 than January 1, 2005, the Secretary shall sub-
7 mit a report to Congress that contains—

8 “(i) an assessment of any incremental
9 cost to group health plans resulting from
10 the provisions of this section;

11 “(ii) a projection of expenditures to
12 such plans resulting from this section;

13 “(iii) an assessment of any impact on
14 premiums resulting from this section; and

15 “(iv) recommendations regarding ac-
16 tion on other diseases.”.

17 (b) CONFORMING AMENDMENT.—The table of con-
18 tents in section 1 of such Act is amended by adding at
19 the end of the items relating to subpart B of part 7 of
20 subtitle B of title I of such Act the following new item:

“Sec. 714. Patient access to unrestricted medical advice, emergency medical
care, obstetric and gynecological care, pediatric care, and con-
tinuity of care.”.

21 **SEC. 102. REQUIRED DISCLOSURE TO NETWORK PRO-**
22 **VIDERS.**

23 (a) IN GENERAL.—Subpart B of part 7 of subtitle
24 B of title I of the Employee Retirement Income Security

1 Act of 1974 (as amended by section 101) is amended fur-
2 ther by adding at the end the following new section:

3 **“SEC. 715. REQUIRED DISCLOSURE TO NETWORK PRO-**
4 **VIDERS.**

5 “(a) IN GENERAL.—If a group health plan reim-
6 burses, through a contract or other arrangement, a health
7 care provider at a discounted payment rate because the
8 provider participates in a provider network, the plan shall
9 disclose to the provider the following information before
10 the provider furnishes covered items or services under the
11 plan:

12 “(1) The identity of the plan sponsor or other
13 entity that is to utilize the discounted payment rates
14 in reimbursing network providers in that network.

15 “(2) The existence of any substantial benefit
16 differentials established for the purpose of actively
17 encouraging participants or beneficiaries under the
18 plan to utilize the providers in that network.

19 “(3) The methods and materials by which pro-
20 viders in the network are identified to such partici-
21 pants or beneficiaries as part of the network.

22 “(b) PERMITTED MEANS OF DISCLOSURE.—Disclo-
23 sure required under subsection (a) by a plan may be
24 made—

1 “(1) by another entity under a contract or
2 other arrangement between the plan and the entity;
3 and

4 “(2) by making such information available in
5 written format, in an electronic format, on the Inter-
6 net, or on a proprietary computer network which is
7 readily accessible to the network providers.

8 “(c) CONSTRUCTION.—Nothing in this section shall
9 be construed to require, directly or indirectly, disclosure
10 of specific fee arrangements or other reimbursement
11 arrangements—

12 “(1) between (i) group health plans or provider
13 networks and (ii) health care providers, or

14 “(2) among health care providers.

15 “(d) DEFINITIONS.—For purposes of this subsection:

16 “(1) BENEFIT DIFFERENTIAL.—The term ‘ben-
17 efit differential’ means, with respect to a group
18 health plan, differences in the case of any partici-
19 pant or beneficiary, in the financial responsibility for
20 payment of coinsurance, copayments, deductibles,
21 balance billing requirements, or any other charge,
22 based upon whether a health care provider from
23 whom covered items or services are obtained is a
24 network provider.

“(2) DISCOUNTED PAYMENT RATE.—The term ‘discounted payment rate’ means, with respect to a provider, a payment rate that is below the charge imposed by the provider.

“(3) NETWORK PROVIDER.—The term ‘network provider’ means, with respect to a group health plan, a health care provider that furnishes health care items and services to participants or beneficiaries under the plan pursuant to a contract or other arrangement with a provider network in which the provider is participating.

“(4) PROVIDER NETWORK.—The term ‘provider network’ means, with respect to a group health plan offering health insurance coverage, an association of network providers through whom the plan provides, through contract or other arrangement, health care items and services to participants and beneficiaries.”.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new item:

“Sec. 715. Required disclosure to network providers.”.

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning

1 on or after January 1 of the second calendar year fol-
2 lowing the date of the enactment of this Act, except that
3 the Secretary of Labor may issue regulations before such
4 date under such amendments. The Secretary shall first
5 issue regulations necessary to carry out the amendments
6 made by this subtitle before the effective date thereof.

7 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
8 enforcement action shall be taken, pursuant to the amend-
9 ments made by this subtitle, against a group health plan
10 or health insurance issuer with respect to a violation of
11 a requirement imposed by such amendments before the
12 date of issuance of regulations issued in connection with
13 such requirement, if the plan or issuer has sought to com-
14 ply in good faith with such requirement.

15 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
16 AGREEMENTS.—In the case of a group health plan main-
17 tained pursuant to one or more collective bargaining
18 agreements between employee representatives and one or
19 more employers ratified before the date of the enactment
20 of this Act, the amendments made by this subtitle shall
21 not apply with respect to plan years beginning before the
22 later of—

23 (1) the date on which the last of the collective
24 bargaining agreements relating to the plan termi-
25 nates (determined without regard to any extension

thereof agreed to after the date of the enactment of this Act); or

(2) January 1, 2002.

For purposes of this subsection, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this subtitle shall not be treated as a termination of such collective bargaining agreement.

Subtitle B—Patient Access to Information

SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING PLAN COVERAGE, MANAGED CARE PROCEDURES, HEALTH CARE PROVIDERS, AND QUALITY OF MEDICAL CARE.

(a) IN GENERAL.—Part 1 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended—

(1) by redesignating section 111 as section 112; and

(2) by inserting after section 110 the following new section:

“DISCLOSURE BY GROUP HEALTH PLANS

“SEC. 111. (a) DISCLOSURE REQUIREMENT.—The administrator of each group health plan shall take such actions as are necessary to ensure that the summary plan

1 description of the plan required under section 102 (or each
2 summary plan description in any case in which different
3 summary plan descriptions are appropriate under part 1
4 for different options of coverage) contains, among any in-
5 formation otherwise required under this part, the informa-
6 tion required under subsections (b), (c), (d), and
7 (e)(2)(A).

8 “(b) PLAN BENEFITS.—The information required
9 under subsection (a) includes the following:

10 “(1) COVERED ITEMS AND SERVICES.—

11 “(A) CATEGORIZATION OF INCLUDED BEN-
12 EFITS.—A description of covered benefits, cat-
13 egorized by—

14 “(i) types of items and services (in-
15 cluding any special disease management
16 program); and

17 “(ii) types of health care professionals
18 providing such items and services.

19 “(B) EMERGENCY MEDICAL CARE.—A de-
20 scription of the extent to which the plan covers
21 emergency medical care (including the extent to
22 which the plan provides for access to urgent
23 care centers), and any definitions provided
24 under the plan for the relevant plan termi-
25 nology referring to such care.

1 “(C) PREVENTATIVE SERVICES.—A de-
2 scription of the extent to which the plan pro-
3 vides benefits for preventative services.

4 “(D) DRUG FORMULARIES.—A description
5 of the extent to which covered benefits are de-
6 termined by the use or application of a drug
7 formulary and a summary of the process for de-
8 termining what is included in such formulary.

9 “(E) COBRA CONTINUATION COV-
10 ERAGE.—A description of the benefits available
11 under the plan pursuant to part 6.

12 “(2) LIMITATIONS, EXCLUSIONS, AND RESTRIC-
13 TIONS ON COVERED BENEFITS.—

14 “(A) CATEGORIZATION OF EXCLUDED
15 BENEFITS.—A description of benefits specifi-
16 cally excluded from coverage, categorized by
17 types of items and services.

18 “(B) UTILIZATION REVIEW AND
19 PREAUTHORIZATION REQUIREMENTS.—Whether
20 coverage for medical care is limited or excluded
21 on the basis of utilization review or
22 preauthorization requirements.

23 “(C) LIFETIME, ANNUAL, OR OTHER PE-
24 RIOD LIMITATIONS.—A description of the cir-
25 cumstances under which, and the extent to

1 which, coverage is subject to lifetime, annual,
2 or other period limitations, categorized by types
3 of benefits.

4 “(D) CUSTODIAL CARE.—A description of
5 the circumstances under which, and the extent
6 to which, the coverage of benefits for custodial
7 care is limited or excluded, and a statement of
8 the definition used by the plan for custodial
9 care.

10 “(E) EXPERIMENTAL TREATMENTS.—
11 Whether coverage for any medical care is lim-
12 ited or excluded because it constitutes an inves-
13 tigational item or experimental treatment or
14 technology, and any definitions provided under
15 the plan for the relevant plan terminology refer-
16 ring to such limited or excluded care.

17 “(F) MEDICAL APPROPRIATENESS OR NE-
18 CESSITY.—Whether coverage for medical care
19 may be limited or excluded by reason of a fail-
20 ure to meet the plan’s requirements for medical
21 appropriateness or necessity, and any defini-
22 tions provided under the plan for the relevant
23 plan terminology referring to such limited or
24 excluded care.

1 “(G) SECOND OR SUBSEQUENT OPIN-
2 IONS.—A description of the circumstances
3 under which, and the extent to which, coverage
4 for second or subsequent opinions is limited or
5 excluded.

6 “(H) SPECIALTY CARE.—A description of
7 the circumstances under which, and the extent
8 to which, coverage of benefits for specialty care
9 is conditioned on referral from a primary care
10 provider.

11 “(I) CONTINUITY OF CARE.—A description
12 of the circumstances under which, and the ex-
13 tent to which, coverage of items and services
14 provided by any health care professional is lim-
15 ited or excluded by reason of the departure by
16 the professional from any defined set of pro-
17 viders.

18 “(J) RESTRICTIONS ON COVERAGE OF
19 EMERGENCY SERVICES.—A description of the
20 circumstances under which, and the extent to
21 which, the plan, in covering emergency medical
22 care furnished to a participant or beneficiary of
23 the plan imposes any financial responsibility de-
24 scribed in subsection (c) on participants or
25 beneficiaries or limits or conditions benefits for

1 such care subject to any other term or condition
2 of such plan.

3 “(3) NETWORK CHARACTERISTICS.—If the plan
4 (or health insurance issuer offering health insurance
5 coverage in connection with the plan) utilizes a de-
6 fined set of providers under contract with the plan
7 (or issuer), a detailed list of the names of such pro-
8 viders and their geographic location, set forth sepa-
9 rately with respect to primary care providers and
10 with respect to specialists.

11 “(c) PARTICIPANT’S FINANCIAL RESPONSIBIL-
12 ITIES.—The information required under subsection (a) in-
13 cludes an explanation of—

14 “(1) a participant’s financial responsibility for
15 payment of premiums, coinsurance, copayments,
16 deductibles, and any other charges; and

17 “(2) the circumstances under which, and the
18 extent to which, the participant’s financial responsi-
19 bility described in paragraph (1) may vary, including
20 any distinctions based on whether a health care pro-
21 vider from whom covered benefits are obtained is in-
22 cluded in a defined set of providers.

23 “(d) DISPUTE RESOLUTION PROCEDURES.—The in-
24 formation required under subsection (a) includes a de-

1 scription of the processes adopted by the plan pursuant
2 to section 503, including—

3 “(1) descriptions thereof relating specifically
4 to—

5 “(A) coverage decisions;

6 “(B) internal review of coverage decisions;

7 and

8 “(C) any external review of coverage deci-
9 sions; and

10 “(2) the procedures and time frames applicable
11 to each step of the processes referred to in subpara-
12 graphs (A), (B), and (C) of paragraph (1).

13 “(e) INFORMATION ON PLAN PERFORMANCE.—Any
14 information required under subsection (a) shall include in-
15 formation concerning the number of external reviews
16 under section 503 that have been completed during the
17 prior plan year and the number of such reviews in which
18 a recommendation is made for modification or reversal of
19 an internal review decision under the plan.

20 “(f) INFORMATION INCLUDED WITH ADVERSE COV-
21 ERAGE DECISIONS.—A group health plan shall provide to
22 each participant and beneficiary, together with any notifi-
23 cation of the participant or beneficiary of an adverse cov-
24 erage decision, the following information:

1 “(1) PREAUTHORIZATION AND UTILIZATION RE-
2 VIEW PROCEDURES.—A description of the basis on
3 which any preauthorization requirement or any utili-
4 zation review requirement has resulted in the ad-
5 verse coverage decision.

6 “(2) PROCEDURES FOR DETERMINING EXCLU-
7 SIONS BASED ON MEDICAL NECESSITY OR ON INVES-
8 TIGATIONAL ITEMS OR EXPERIMENTAL TREAT-
9 MENTS.—If the adverse coverage decision is based
10 on a determination relating to medical necessity or
11 to an investigational item or an experimental treat-
12 ment or technology, a description of the procedures
13 and medically-based criteria used in such decision.

14 “(g) INFORMATION AVAILABLE ON REQUEST.—

15 “(1) ACCESS TO PLAN BENEFIT INFORMATION
16 IN ELECTRONIC FORM.—

17 “(A) IN GENERAL.—In addition to the in-
18 formation required to be provided under section
19 104(b)(4), a group health plan may, upon writ-
20 ten request (made not more frequently than an-
21 nually), make available to participants and
22 beneficiaries, in a generally recognized elec-
23 tronic format—

1 “(i) the latest summary plan descrip-
2 tion, including the latest summary of ma-
3 terial modifications, and

4 “(ii) the actual plan provisions setting
5 forth the benefits available under the plan,
6 to the extent such information relates to the
7 coverage options under the plan available to the
8 participant or beneficiary. A reasonable charge
9 may be made to cover the cost of providing
10 such information in such generally recognized
11 electronic format. The Secretary may by regula-
12 tion prescribe a maximum amount which will
13 constitute a reasonable charge under the pre-
14 ceding sentence.

15 “(B) ALTERNATIVE ACCESS.—The require-
16 ments of this paragraph may be met by making
17 such information generally available (rather
18 than upon request) on the Internet or on a pro-
19 prietary computer network in a format which is
20 readily accessible to participants and bene-
21 ficiaries.

22 “(2) ADDITIONAL INFORMATION TO BE PRO-
23 VIDED ON REQUEST.—

24 “(A) INCLUSION IN SUMMARY PLAN DE-
25 SCRIPTION OF SUMMARY OF ADDITIONAL IN-

1 FORMATION.—The information required under
2 subsection (a) includes a summary description
3 of the types of information required by this
4 subsection to be made available to participants
5 and beneficiaries on request.

6 “(B) INFORMATION REQUIRED FROM
7 PLANS AND ISSUERS ON REQUEST.—In addition
8 to information required to be included in sum-
9 mary plan descriptions under this subsection, a
10 group health plan shall provide the following in-
11 formation to a participant or beneficiary on re-
12 quest:

13 “(i) CARE MANAGEMENT INFORMA-
14 TION.—A description of the circumstances
15 under which, and the extent to which, the
16 plan has special disease management pro-
17 grams or programs for persons with dis-
18 abilities, indicating whether these pro-
19 grams are voluntary or mandatory and
20 whether a significant benefit differential
21 results from participation in such pro-
22 grams.

23 “(ii) INCLUSION OF DRUGS AND
24 BIOLOGICALS IN FORMULARIES.—A state-
25 ment of whether a specific drug or biologi-

1 cal is included in a formulary used to de-
2 termine benefits under the plan and a de-
3 scription of the procedures for considering
4 requests for any patient-specific waivers.

5 “(iii) ACCREDITATION STATUS OF
6 HEALTH INSURANCE ISSUERS AND SERV-
7 ICE PROVIDERS.—A description of the ac-
8 creditation and licensing status (if any) of
9 each health insurance issuer offering
10 health insurance coverage in connection
11 with the plan and of any utilization review
12 organization utilized by the issuer or the
13 plan, together with the name and address
14 of the accrediting or licensing authority.

15 “(iv) QUALITY PERFORMANCE MEAS-
16 URES.—The latest information (if any)
17 maintained by the plan relating to quality
18 of performance of the delivery of medical
19 care with respect to coverage options of-
20 fered under the plan and of health care
21 professionals and facilities providing med-
22 ical care under the plan.

23 “(C) INFORMATION REQUIRED FROM
24 HEALTH CARE PROFESSIONALS.—

1 “(i) QUALIFICATIONS, PRIVILEGES,
2 AND METHOD OF COMPENSATION.—Any
3 health care professional treating a partici-
4 pant or beneficiary under a group health
5 plan shall provide to the participant or
6 beneficiary, on request, a description of his
7 or her professional qualifications (including
8 board certification status, licensing status,
9 and accreditation status, if any), privileges,
10 and experience and a general description
11 by category (including salary, fee-for-serv-
12 ice, capitation, and such other categories
13 as may be specified in regulations of the
14 Secretary) of the applicable method by
15 which such professional is compensated in
16 connection with the provision of such med-
17 ical care.

18 “(ii) COST OF PROCEDURES.—Any
19 health care professional who recommends
20 an elective procedure or treatment while
21 treating a participant or beneficiary under
22 a group health plan that requires a partici-
23 pant or beneficiary to share in the cost of
24 treatment shall inform such participant or
25 beneficiary of each cost associated with the

1 procedure or treatment and an estimate of
2 the magnitude of such costs.

3 “(D) INFORMATION REQUIRED FROM
4 HEALTH CARE FACILITIES ON REQUEST.—Any
5 health care facility from which a participant or
6 beneficiary has sought treatment under a group
7 health plan shall provide to the participant or
8 beneficiary, on request, a description of the fa-
9 cility’s corporate form or other organizational
10 form and all forms of licensing and accredita-
11 tion status (if any) assigned to the facility by
12 standard-setting organizations.

13 “(h) ACCESS TO INFORMATION RELEVANT TO THE
14 COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT
15 OR BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition
16 to information otherwise required to be made available
17 under this section, a group health plan shall, upon written
18 request (made not more frequently than annually), make
19 available to a participant (and an employee who, under
20 the terms of the plan, is eligible for coverage but not en-
21 rolled) in connection with a period of enrollment the sum-
22 mary plan description for any coverage option under the
23 plan under which the participant is eligible to enroll and
24 any information described in clauses (i), (ii), (iii), (vi),
25 (vii), and (viii) of subsection (e)(2)(B).

1 “(i) ADVANCE NOTICE OF CHANGES IN DRUG
2 FORMULARIES.—Not later than 30 days before the effec-
3 tive of date of any exclusion of a specific drug or biological
4 from any drug formulary under the plan that is used in
5 the treatment of a chronic illness or disease, the plan shall
6 take such actions as are necessary to reasonably ensure
7 that plan participants are informed of such exclusion. The
8 requirements of this subsection may be satisfied—

9 “(1) by inclusion of information in publications
10 broadly distributed by plan sponsors, employers, or
11 employee organizations;

12 “(2) by electronic means of communication (in-
13 cluding the Internet or proprietary computer net-
14 works in a format which is readily accessible to par-
15 ticipants);

16 “(3) by timely informing participants who,
17 under an ongoing program maintained under the
18 plan, have submitted their names for such notifica-
19 tion; or

20 “(4) by any other reasonable means of timely
21 informing plan participants.

22 “(j) DEFINITIONS AND RELATED RULES.—

23 “(1) IN GENERAL.—For purposes of this
24 section—

1 “(A) GROUP HEALTH PLAN.—The term
2 ‘group health plan’ has the meaning provided
3 such term under section 733(a)(1).

4 “(B) MEDICAL CARE.—The term ‘medical
5 care’ has the meaning provided such term
6 under section 733(a)(2).

7 “(C) HEALTH INSURANCE COVERAGE.—
8 The term ‘health insurance coverage’ has the
9 meaning provided such term under section
10 733(b)(1).

11 “(D) HEALTH INSURANCE ISSUER.—The
12 term ‘health insurance issuer’ has the meaning
13 provided such term under section 733(b)(2).

14 “(2) APPLICABILITY ONLY IN CONNECTION
15 WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

16 “(A) IN GENERAL.—The requirements of
17 this section shall apply only in connection with
18 included group health plan benefits.

19 “(B) INCLUDED GROUP HEALTH PLAN
20 BENEFIT.—For purposes of subparagraph (A),
21 the term ‘included group health plan benefit’
22 means a benefit which is not an excepted ben-
23 efit (as defined in section 733(c)).”.

24 (b) CONFORMING AMENDMENTS.—

1 (1) Section 102(b) of such Act (29 U.S.C.
 2 1022(b)) is amended by inserting before the period
 3 at the end the following: “; and, in the case of a
 4 group health plan (as defined in section 111(i)(1)),
 5 the information required to be included under sec-
 6 tion 111(a)”.

7 (2) The table of contents in section 1 of such
 8 Act is amended by striking the item relating to sec-
 9 tion 111 and inserting the following new items:

“Sec. 111. Disclosure by group health plans.

“Sec. 112. Repeal and effective date.”.

10 **SEC. 112. EFFECTIVE DATE AND RELATED RULES.**

11 (a) IN GENERAL.—The amendments made by this
 12 subtitle shall apply with respect to plan years beginning
 13 on or after January 1 of the second calendar year fol-
 14 lowing the date of the enactment of this Act. The Sec-
 15 retary of Labor shall first issue all regulations necessary
 16 to carry out the amendments made by this subtitle before
 17 such date.

18 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
 19 enforcement action shall be taken, pursuant to the amend-
 20 ments made by this subtitle, against a group health plan
 21 or health insurance issuer with respect to a violation of
 22 a requirement imposed by such amendments before the
 23 date of issuance of final regulations issued in connection

1 with such requirement, if the plan or issuer has sought
2 to comply in good faith with such requirement.

3 **Subtitle C—Group Health Plan** 4 **Review Standards**

5 **SEC. 121. SPECIAL RULES FOR GROUP HEALTH PLANS.**

6 (a) IN GENERAL.—Section 503 of the Employee Re-
7 tirement Income Security Act of 1974 (29 U.S.C. 1133)
8 is amended—

9 (1) by inserting “(a) IN GENERAL.—” after
10 “SEC. 503.”;

11 (2) by inserting (after and below paragraph
12 (2)) the following new flush-left sentence:

13 “This subsection does not apply in the case of included
14 group health plan benefits (as defined in subsection
15 (b)(10)(S)).”; and

16 (3) by adding at the end the following new sub-
17 section:

18 “(b) SPECIAL RULES FOR GROUP HEALTH PLANS.—

19 “(1) COVERAGE DETERMINATIONS.—Every
20 group health plan shall, in the case of included
21 group health plan benefits—

22 “(A) provide adequate notice in writing in
23 accordance with this subsection to any partici-
24 pant or beneficiary of any adverse coverage de-
25 cision with respect to such benefits of such par-

1 ticipant or beneficiary under the plan, setting
2 forth the specific reasons for such coverage de-
3 cision and any rights of review provided under
4 the plan, written in a manner calculated to be
5 understood by the average participant;

6 “(B) provide such notice in writing also to
7 any treating medical care provider of such par-
8 ticipant or beneficiary, if such provider has
9 claimed reimbursement for any item or service
10 involved in such coverage decision, or if a claim
11 submitted by the provider initiated the pro-
12 ceedings leading to such decision;

13 “(C) afford a reasonable opportunity to
14 any participant or beneficiary who is in receipt
15 of the notice of such adverse coverage decision,
16 and who files a written request for review of the
17 initial coverage decision within 90 days after re-
18 ceipt of the notice of the initial decision, for a
19 full and fair review of the decision by an appro-
20 priate named fiduciary who did not make the
21 initial decision; and

22 “(D) meet the additional requirements of
23 this subsection, which shall apply solely with re-
24 spect to such benefits.

1 “(2) TIME LIMITS FOR MAKING INITIAL COV-
2 ERAGE DECISIONS FOR BENEFITS AND COMPLETING
3 INTERNAL APPEALS.—

4 “(A) TIME LIMITS FOR DECIDING RE-
5 QUESTS FOR BENEFIT PAYMENTS, REQUESTS
6 FOR ADVANCE DETERMINATION OF COVERAGE,
7 AND REQUESTS FOR REQUIRED DETERMINA-
8 TION OF MEDICAL NECESSITY.—Except as pro-
9 vided in subparagraph (B)—

10 “(i) INITIAL DECISIONS.—If a request
11 for benefit payments, a request for advance
12 determination of coverage, or a request for
13 required determination of medical necessity
14 is submitted to a group health plan in such
15 reasonable form as may be required under
16 the plan, the plan shall issue in writing an
17 initial coverage decision on the request be-
18 fore the end of the initial decision period
19 under paragraph (10)(I) following the fil-
20 ing completion date. Failure to issue a cov-
21 erage decision on such a request before the
22 end of the period required under this
23 clause shall be treated as an adverse cov-
24 erage decision for purposes of internal re-
25 view under clause (ii).

1 “(ii) INTERNAL REVIEWS OF INITIAL
2 DENIALS.—Upon the written request of a
3 participant or beneficiary for review of an
4 initial adverse coverage decision under
5 clause (i), a review by an appropriate
6 named fiduciary (subject to paragraph (3))
7 of the initial coverage decision shall be
8 completed, including issuance by the plan
9 of a written decision affirming, reversing,
10 or modifying the initial coverage decision,
11 setting forth the grounds for such decision,
12 before the end of the internal review period
13 following the review filing date. Such deci-
14 sion shall be treated as the final decision
15 of the plan, subject to any applicable re-
16 consideration under paragraph (4). Failure
17 to issue before the end of such period such
18 a written decision requested under this
19 clause shall be treated as a final decision
20 affirming the initial coverage decision.

21 “(B) TIME LIMITS FOR MAKING COVERAGE
22 DECISIONS RELATING TO ACCELERATED NEED
23 MEDICAL CARE AND FOR COMPLETING INTER-
24 NAL APPEALS.—

1 “(i) INITIAL DECISIONS.—A group
2 health plan shall issue in writing an initial
3 coverage decision on any request for expedited advance determination of coverage or
4 for expedited required determination of
5 medical necessity submitted, in such reasonable form as may be required under the
6 plan before the end of the accelerated need
7 decision period under paragraph (10)(K),
8 in cases involving accelerated need medical
9 care, following the filing completion date.
10 Failure to approve or deny such a request
11 before the end of the applicable decision
12 period shall be treated as a denial of the
13 request for purposes of internal review
14 under clause (ii).

17 “(ii) INTERNAL REVIEWS OF INITIAL
18 DENIALS.—Upon the written request of a
19 participant or beneficiary for review of an
20 initial adverse coverage decision under
21 clause (i), a review by an appropriate
22 named fiduciary (subject to paragraph (3))
23 of the initial coverage decision shall be
24 completed, including issuance by the plan
25 of a written decision affirming, reversing,

1 or modifying the initial converge decision,
2 setting forth the grounds for the decision
3 before the end of the accelerated need deci-
4 sion period under paragraph (10)(K) fol-
5 lowing the review filing date. Such decision
6 shall be treated as the final decision of the
7 plan, subject to any applicable reconsider-
8 ation under paragraph (4). Failure to issue
9 before the end of the applicable decision
10 period such a written decision requested
11 under this clause shall be treated as a final
12 decision affirming the initial coverage deci-
13 sion.

14 “(3) PHYSICIANS MUST REVIEW INITIAL COV-
15 ERAGE DECISIONS INVOLVING MEDICAL APPRO-
16 PRIATENESS OR NECESSITY OR INVESTIGATIONAL
17 ITEMS OR EXPERIMENTAL TREATMENT.—If an ini-
18 tial coverage decision under paragraph (2)(A)(i) or
19 (2)(B)(i) is based on a determination that provision
20 of a particular item or service is excluded from cov-
21 erage under the terms of the plan because the provi-
22 sion of such item or service does not meet the re-
23 quirements for medical appropriateness or necessity
24 or would constitute provision of investigational items
25 or experimental treatment or technology, the review

1 under paragraph (2)(A)(ii) or (2)(B)(ii), to the ex-
2 tent that it relates to medical appropriateness or ne-
3 cessity or to investigational items or experimental
4 treatment or technology, shall be conducted by a
5 physician who is selected by the plan and who did
6 not make the initial denial.

7 “(4) ELECTIVE EXTERNAL REVIEW BY INDE-
8 PENDENT MEDICAL EXPERT AND RECONSIDERATION
9 OF INITIAL REVIEW DECISION.—

10 “(A) IN GENERAL.—In any case in which
11 a participant or beneficiary, who has received
12 an adverse coverage decision which is not re-
13 versed upon review conducted pursuant to para-
14 graph (1)(C) (including review under paragraph
15 (2)(A)(ii) or (2)(B)(ii)) and who has not com-
16 menced review of the coverage decision under
17 section 502, makes a request in writing, within
18 30 days after the date of such review decision,
19 for reconsideration of such review decision, the
20 requirements of subparagraphs (B), (C), (D)
21 and (E) shall apply in the case of such adverse
22 coverage decision, if the requirements of clause
23 (i) or (ii) are met, subject to clause (iii).

24 “(i) MEDICAL APPROPRIATENESS OR
25 INVESTIGATIONAL ITEM OR EXPERI-

1 MENTAL TREATMENT OR TECHNOLOGY.—

2 The requirements of this clause are met if
3 such coverage decision is based on a deter-
4 mination that provision of a particular
5 item or service that would otherwise be
6 covered is excluded from coverage because
7 the provision of such item or service—

8 “(I) is not medically appropriate
9 or necessary; or

10 “(II) would constitute provision
11 of an investigational item or experi-
12 mental treatment or technology.

13 “(ii) EXCLUSION OF ITEM OR SERVICE
14 REQUIRING EVALUATION OF MEDICAL
15 FACTS OR EVIDENCE.—The requirements
16 of this clause are met if—

17 “(I) such coverage decision is
18 based on a determination that a par-
19 ticular item or service is not covered
20 under the terms of the plan because
21 provision of such item or service is
22 specifically or categorically excluded
23 from coverage under the terms of the
24 plan, and

1 “(II) an independent contract ex-
2 pert finds under subparagraph (C), in
3 advance of any review of the decision
4 under subparagraph (D), that such
5 determination primarily requires the
6 evaluation of medical facts or medical
7 evidence by a health professional.

8 “(iii) MATTERS SPECIFICALLY NOT
9 SUBJECT TO REVIEW.—The requirements
10 of subparagraphs (B), (C), (D), and (E)
11 shall not apply in the case of any adverse
12 coverage decision if such decision is based
13 on—

14 “(I) a determination of eligibility
15 for benefits,

16 “(II) the application of explicit
17 plan limits on the number, cost, or
18 duration of any benefit, or

19 “(III) a limitation on the amount
20 of any benefit payment or a require-
21 ment to make copayments under the
22 terms of the plan.

23 Review under this paragraph shall not be avail-
24 able for any coverage decision that has pre-
25 viously undergone review under this paragraph.

1 “(B) LIMITS ON ALLOWABLE ADVANCE
2 PAYMENTS.—The review under this paragraph
3 in connection with an adverse coverage decision
4 shall be available subject to any requirement of
5 the plan (unless waived by the plan for financial
6 or other reasons) for payment in advance to the
7 plan by the participant or beneficiary seeking
8 review of an amount not to exceed the greater
9 of—

10 “(i) the lesser of \$100 or 10 percent
11 of the cost of the medical care involved in
12 the decision, or

13 “(ii) \$25,
14 with such dollar amount subject to compounded
15 annual adjustments in the same manner and to
16 the same extent as apply under section 215(i)
17 of the Social Security Act, except that, for any
18 calendar year, such amount as so adjusted shall
19 be deemed, solely for such calendar year, to be
20 equal to such amount rounded to the nearest
21 \$10. No such payment may be required in the
22 case of any participant or beneficiary whose en-
23 rollment under the plan is paid for, in whole or
24 in part, under a State plan under title XIX or
25 XXI of the Social Security Act. Any such ad-

1 vance payment shall be subject to reimburse-
2 ment if the recommendation of the independent
3 medical expert (or panel of such experts) under
4 subparagraph (D)(ii)(IV) is to reverse or mod-
5 ify the coverage decision.

6 “(C) REQUEST TO INDEPENDENT CON-
7 TRACT EXPERT FOR DETERMINATION OF
8 WHETHER COVERAGE DECISION REQUIRED
9 EVALUATION OF MEDICAL FACTS OR EVI-
10 DENCE.—

11 “(i) IN GENERAL.—In the case of a
12 request for review made by a participant or
13 beneficiary as described in subparagraph
14 (A), if the requirements of subparagraph
15 (A)(ii) are met (and review is not other-
16 wise precluded under subparagraph
17 (A)(iii)), the terms of the plan shall pro-
18 vide for a procedure for initial review by
19 an independent contract expert selected in
20 accordance with subparagraph (H) under
21 which the expert will determine whether
22 the coverage decision requires the evalua-
23 tion of medical facts or evidence by a
24 health professional. If the expert deter-
25 mines that the coverage decision requires

1 such evaluation, reconsideration of such
2 adverse decision shall proceed under this
3 paragraph. If the expert determines that
4 the coverage decision does not require such
5 evaluation, the adverse decision shall re-
6 main the final decision of the plan.

7 “(ii) INDEPENDENT CONTRACT EX-
8 PERTS.—For purposes of this subpara-
9 graph, the term ‘independent contract ex-
10 pert’ means a professional—

11 “(I) who has appropriate creden-
12 tials and has attained recognized ex-
13 pertise in the applicable area of con-
14 tract interpretation;

15 “(II) who was not involved in the
16 initial decision or any earlier review
17 thereof; and

18 “(III) who is selected in accord-
19 ance with subparagraph (H)(i) and
20 meets the requirements of subpara-
21 graph (H)(iii).

22 “(D) RECONSIDERATION OF INITIAL RE-
23 VIEW DECISION.—

24 “(i) IN GENERAL.—In the case of a
25 request for review made by a participant or

1 beneficiary as described in subparagraph
2 (A), if the requirements of subparagraph
3 (A)(i) are met or reconsideration proceeds
4 under this paragraph pursuant to subpara-
5 graph (C), the terms of the plan shall pro-
6 vide for a procedure for such reconsider-
7 ation in accordance with clause (ii).

8 “(ii) PROCEDURE FOR RECONSIDER-
9 ATION.—The procedure required under
10 clause (i) shall include the following—

11 “(I) An independent medical ex-
12 pert (or a panel of such experts, as
13 determined necessary) will be selected
14 in accordance with subparagraph (H)
15 to reconsider any coverage decision
16 described in subparagraph (A) to de-
17 termine whether such decision was in
18 accordance with the terms of the plan
19 and this title.

20 “(II) The record for review (in-
21 cluding a specification of the terms of
22 the plan and other criteria serving as
23 the basis for the initial review deci-
24 sion) will be presented to such expert
25 (or panel) and maintained in a man-

1 ner which will ensure confidentiality
2 of such record.

3 “(III) Such expert (or panel) will
4 reconsider the initial review decision
5 to determine whether such decision
6 was in accordance with the terms of
7 the plan and this title. The expert (or
8 panel) in its reconsideration will take
9 into account the medical condition of
10 the patient, the recommendation of
11 the treating physician, the initial cov-
12 erage decision (including the reasons
13 for such decision) and the decision
14 upon review conducted pursuant to
15 paragraph (1)(C) (including review
16 under paragraph (2)(A)(ii) or
17 (2)(B)(ii)) , any guidelines adopted by
18 the plan through a process involving
19 medical practitioners and peer-re-
20 viewed medical literature identified as
21 such under criteria established by the
22 Food and Drug Administration, and
23 any other valid, relevant, scientific or
24 clinical evidence the expert (or panel)
25 determines appropriate for its review.

1 The expert (or panel) may consult the
2 participant or beneficiary, the treating
3 physician, the medical director of the
4 plan, or any other party who, in the
5 opinion of the expert (or panel), may
6 have relevant information for consid-
7 eration.

8 “(E) ISSUANCE OF BINDING FINAL
9 DECISION.—Upon completion of the proce-
10 dure for review under subparagraph (D),
11 the independent medical expert (or panel
12 of such experts) shall issue a written deci-
13 sion affirming, modifying, or reversing the
14 initial review decision, setting forth the
15 grounds for the decision. Such decision
16 shall be the final decision of the plan and
17 shall be binding on the plan. Such decision
18 shall set forth specifically the determina-
19 tion of the expert (or panel) of the appro-
20 priate period for timely compliance by the
21 plan with the decision. Such decision shall
22 be issued concurrently to the participant or
23 beneficiary, to the treating physician, and
24 to the plan, shall constitute conclusive,
25 written authorization for the provision of

1 benefits under the plan in accordance with
2 the decision, and shall be treated as terms
3 of the plan for purposes of any action by
4 the participant or beneficiary under section
5 502.

6 “(F) TIME LIMITS FOR RECONSIDER-
7 ATION.—Any review under this paragraph (in-
8 cluding any review under subparagraph (C))
9 shall be completed before the end of the recon-
10 sideration period (as defined in paragraph
11 (10)(L)) following the review filing date in con-
12 nection with such review. Failure to issue a
13 written decision before the end of the reconsid-
14 eration period in any reconsideration requested
15 under this paragraph shall be treated as a final
16 decision affirming the initial review decision of
17 the plan.

18 “(G) INDEPENDENT MEDICAL EXPERTS.—

19 “(i) IN GENERAL.—For purposes of
20 this paragraph, the term ‘independent
21 medical expert’ means, in connection with
22 any coverage decision by a group health
23 plan, a professional—

1 “(I) who is a physician or, if ap-
2 propriate, another medical profes-
3 sional,

4 “(II) who has appropriate cre-
5 dentials and has attained recognized
6 expertise in the applicable medical
7 field,

8 “(III) who was not involved in
9 the initial decision or any earlier re-
10 view thereof,

11 “(IV) who has no history of dis-
12 ciplinary action or sanctions (includ-
13 ing, but not limited to, loss of staff
14 privileges or participation restriction)
15 taken or pending by any hospital,
16 health carrier, government, or regu-
17 latory body, and

18 “(V) who is selected in accord-
19 ance with subparagraph (H)(i) and
20 meets the requirements of subpara-
21 graph (H)(iii).

22 “(H) SELECTION OF EXPERTS.—

23 “(i) IN GENERAL.—An independent
24 contract expert or independent medical ex-
25 pert (or each member of any panel of inde-

pendent medical experts selected under subparagraph (D)(ii)) is selected in accordance with this clause if—

“(I) the expert is selected by an intermediary which itself meets the requirements of clauses (ii) and (iii), by means of a method which ensures that the identity of the expert is not disclosed to the plan, any health insurance issuer offering health insurance coverage to the aggrieved participant or beneficiary in connection with the plan, and the aggrieved participant or beneficiary under the plan, and the identities of the plan, the issuer, and the aggrieved participant or beneficiary are not disclosed to the expert;

“(II) the expert is selected by an appropriately credentialed panel of physicians meeting the requirements of clauses (ii) and (iii) established by a fully accredited teaching hospital meeting such requirements;

“(III) the expert is selected by an organization described in section

1 1152(1)(A) of the Social Security Act
2 which meets the requirements of
3 clauses (ii) and (iii);

4 “(IV) the expert is selected by an
5 external review organization which
6 meets the requirements of clauses (ii)
7 and (iii) and is accredited by a private
8 standard-setting organization meeting
9 such requirements;

10 “(V) the expert is selected by a
11 State agency which is established for
12 the purpose of conducting independent
13 external reviews and which meets the
14 requirements of clauses (ii) and (iii);
15 or

16 “(VI) the expert is selected, by
17 an intermediary or otherwise, in a
18 manner that is, under regulations
19 issued pursuant to negotiated rule-
20 making, sufficient to ensure the ex-
21 pert’s independence, and the method
22 of selection is devised to reasonably
23 ensure that the expert selected meets
24 the requirements of clauses (ii) and
25 (iii).

1 “(ii) STANDARDS OF PERFORMANCE
2 FOR INTERMEDIARIES.—The Secretary
3 shall prescribe by regulation standards (in
4 addition to the requirements of clause (iii))
5 which entities making selections under sub-
6 clause (I), (II), (III), (IV), (V), or (VI) of
7 clause (ii) must meet in order to be eligible
8 for making such selections. Such standards
9 shall include (but are not limited to)—

10 “(I) assurance that the entity
11 will carry out specified duties in the
12 course of exercising the entity’s re-
13 sponsibilities under clause (i)(I),

14 “(II) assurance that applicable
15 deadlines will be met in the exercise of
16 such responsibilities, and

17 “(III) assurance that the entity
18 meets appropriate indicators of sol-
19 vency and fiscal integrity.

20 Each such entity shall provide to the Sec-
21 retary, in such manner and at such times
22 as the Secretary may prescribe, informa-
23 tion relating the volume of claims with re-
24 spect to which the entity has served under
25 this subparagraph, the types of such

1 claims, and such other information regard-
2 ing such claims as the Secretary may de-
3 termine appropriate.

4 “(iii) INDEPENDENCE REQUIRE-
5 MENTS.—An independent contract expert
6 or independent medical expert or another
7 entity described in clause (i) meets the
8 independence requirements of this clause
9 if—

10 “(I) the expert or entity is not
11 affiliated with any related party;

12 “(II) any compensation received
13 by such expert or entity in connection
14 with the external review is reasonable
15 and not contingent on any decision
16 rendered by the expert or entity;

17 “(III) under the terms of the
18 plan and any health insurance cov-
19 erage offered in connection with the
20 plan, the plan and the issuer (if any)
21 have no recourse against the expert or
22 entity in connection with the external
23 review; and

24 “(IV) the expert or entity does
25 not otherwise have a conflict of inter-

1 est with a related party as determined
2 under any regulations which the Sec-
3 retary may prescribe.

4 “(iv) RELATED PARTY.—For purposes
5 of clause (i)(I), the term ‘related party’
6 means—

7 “(I) the plan or any health insur-
8 ance issuer offering health insurance
9 coverage in connection with the plan
10 (or any officer, director, or manage-
11 ment employee of such plan or issuer);

12 “(II) the physician or other med-
13 ical care provider that provided the
14 medical care involved in the coverage
15 decision;

16 “(III) the institution at which
17 the medical care involved in the cov-
18 erage decision is provided;

19 “(IV) the manufacturer of any
20 drug or other item that was included
21 in the medical care involved in the
22 coverage decision; or

23 “(V) any other party determined
24 under any regulations which the Sec-
25 retary may prescribe to have a sub-

1 stantial interest in the coverage deci-
2 sion.

3 “(v) AFFILIATED.—For purposes of
4 clause (ii)(I), the term ‘affiliated’ means,
5 in connection with any entity, having a fa-
6 miliar, financial, or professional relation-
7 ship with, or interest in, such entity.

8 “(I) MISBEHAVIOR BY EXPERTS.—Any ac-
9 tion by the expert or experts in applying for
10 their selection under this paragraph or in the
11 course of carrying out their duties under this
12 paragraph which constitutes—

13 “(i) fraud or intentional misrepresen-
14 tation by such expert or experts, or

15 “(ii) demonstrates failure to adhere to
16 the standards for selection set forth in sub-
17 paragraph (H)(iii),
18 shall be treated as a failure to meet the require-
19 ments of this paragraph and therefore as a
20 cause of action which may be brought by a fidu-
21 ciary under section 502(a)(3).

22 “(J) BENEFIT EXCLUSIONS MAIN-
23 TAINED.—Nothing in this paragraph shall be
24 construed as providing for or requiring the cov-
25 erage of items or services for which benefits are

1 specifically excluded under the group health
2 plan or any health insurance coverage offered in
3 connection with the plan.

4 “(5) PERMITTED ALTERNATIVES TO REQUIRED
5 FORMS OF REVIEW.—

6 “(A) IN GENERAL.—In accordance with
7 such regulations (if any) as may be prescribed
8 by the Secretary for purposes of this paragraph,
9 in the case of any initial coverage decision or
10 any decision upon review thereof under para-
11 graph (2)(A)(ii) or (2)(B)(ii), a group health
12 plan may provide an alternative dispute resolu-
13 tion procedure meeting the requirements of sub-
14 paragraph (B) for use in lieu of the procedures
15 set forth under the preceding provisions of this
16 subsection relating review of such decision.
17 Such procedure may be provided in one form
18 for all participants and beneficiaries or in a dif-
19 ferent form for each group of similarly situated
20 participants and beneficiaries. Upon voluntary
21 election of such procedure by the plan and by
22 the aggrieved participant or beneficiary in con-
23 nection with the decision, the plan may provide
24 under such procedure (in a manner consistent
25 with such regulations as the Secretary may pre-

1 scribe to ensure equitable procedures) for waiv-
2 er of the review of the decision under paragraph
3 (3) or waiver of further review of the decision
4 under paragraph (4) or section 502 or for elec-
5 tion by such parties of an alternative means of
6 external review (other than review under para-
7 graph (4)).

8 “(B) REQUIREMENTS.—An alternative dis-
9 pute resolution procedure meets the require-
10 ments of this subparagraph, in connection with
11 any decision, if—

12 “(i) such procedure is utilized solely—

13 “(I) in accordance with the appli-
14 cable terms of a bona fide collective
15 bargaining agreement pursuant to
16 which the plan (or the applicable por-
17 tion thereof governed by the agree-
18 ment) is established or maintained, or

19 “(II) upon election by both the
20 aggrieved participant or beneficiary
21 and the plan,

22 “(ii) the procedure incorporates any
23 otherwise applicable requirement for review
24 by a physician under paragraph (3), unless
25 waived by the participant or beneficiary (in

1 a manner consistent with such regulations
2 as the Secretary may prescribe to ensure
3 equitable procedures); and

4 “(iii) the means of resolution of dis-
5 pute allow for adequate presentation by
6 each party of scientific and medical evi-
7 dence supporting the position of such
8 party.

9 “(6) REVIEW REQUIREMENTS.—In any review
10 of a decision issued under this subsection—

11 “(A) the record shall be maintained for
12 purposes of any further review in accordance
13 with standards which shall be prescribed in reg-
14 ulations of the Secretary designed to facilitate
15 such further review, and

16 “(B) any decision upon review which modi-
17 fies or reverses a decision below shall specifi-
18 cally set forth a determination that the record
19 upon review is sufficient to rebut a presumption
20 in favor of the decision below.

21 “(7) COMPLIANCE WITH FIDUCIARY STAND-
22 ARDS.—The issuance of a decision under a plan
23 upon review in good faith compliance with the re-
24 quirements of this subsection shall not be treated as

1 a violation of part 4 of subtitle B of title I of the
2 Employee Retirement Income Security Act of 1974.

3 “(8) LIMITATION ON APPLICABILITY OF SPE-
4 CIAL RULES.—The preceding provisions of this sub-
5 section shall not apply with respect to employee ben-
6 efit plans that are not group health plans or with re-
7 spect to benefits that are not included group health
8 plan benefits (as defined in paragraph (10)(S)).

9 “(9) GROUP HEALTH PLAN DEFINED.—For
10 purposes of this section—

11 “(A) IN GENERAL.—The term ‘group
12 health plan’ shall have the meaning provided in
13 section 733(a).

14 “(B) TREATMENT OF PARTNERSHIPS.—
15 The provisions of paragraphs (1), (2), and (3)
16 of section 732(d) shall apply.

17 “(10) OTHER DEFINITIONS.—For purposes of
18 this subsection—

19 “(A) REQUEST FOR BENEFIT PAY-
20 MENTS.—The term ‘request for benefit pay-
21 ments’ means a request, for payment of benefits
22 by a group health plan for medical care, which
23 is made by, or (if expressly authorized) on be-
24 half of, a participant or beneficiary after such
25 medical care has been provided.

1 “(B) REQUIRED DETERMINATION OF MED-
2 ICAL NECESSITY.—The term ‘required deter-
3 mination of medical necessity’ means a deter-
4 mination required under a group health plan
5 solely that proposed medical care meets, under
6 the facts and circumstances at the time of the
7 determination, the requirements for medical ap-
8 propriateness or necessity (which may be sub-
9 ject to exceptions under the plan for fraud or
10 misrepresentation), irrespective of whether the
11 proposed medical care otherwise meets other
12 terms and conditions of coverage, but only if
13 such determination does not constitute an ad-
14 vance determination of coverage (as defined in
15 subparagraph (C)).

16 “(C) ADVANCE DETERMINATION OF COV-
17 ERAGE.—The term ‘advance determination of
18 coverage’ means a determination under a group
19 health plan that proposed medical care meets,
20 under the facts and circumstances at the time
21 of the determination, the plan’s terms and con-
22 ditions of coverage (which may be subject to ex-
23 ceptions under the plan for fraud or misrepre-
24 sentation).

1 “(D) REQUEST FOR ADVANCE DETERMINA-
2 TION OF COVERAGE.—The term ‘request for ad-
3 vance determination of coverage’ means a re-
4 quest for an advance determination of coverage
5 of medical care which is made by, or (if ex-
6 pressly authorized) on behalf of, a participant
7 or beneficiary before such medical care is pro-
8 vided.

9 “(E) REQUEST FOR EXPEDITED ADVANCE
10 DETERMINATION OF COVERAGE.—The term ‘re-
11 quest for expedited advance determination of
12 coverage’ means a request for advance deter-
13 mination of coverage, in any case in which the
14 proposed medical care constitutes accelerated
15 need medical care.

16 “(F) REQUEST FOR REQUIRED DETER-
17 MINATION OF MEDICAL NECESSITY.—The term
18 ‘request for required determination of medical
19 necessity’ means a request for a required deter-
20 mination of medical necessity for medical care
21 which is made by or on behalf of a participant
22 or beneficiary before the medical care is pro-
23 vided.

24 “(G) REQUEST FOR EXPEDITED REQUIRED
25 DETERMINATION OF MEDICAL NECESSITY.—

1 The term 'request for expedited required deter-
2 mination of medical necessity' means a request
3 for required determination of medical necessity
4 in any case in which the proposed medical care
5 constitutes accelerated need medical care.

6 “(H) ACCELERATED NEED MEDICAL
7 CARE.—The term 'accelerated need medical
8 care' means medical care in any case in which
9 an appropriate physician has certified in writing
10 (or as otherwise provided in regulations of the
11 Secretary) that the participant or beneficiary is
12 stabilized and—

13 “(i) that failure to immediately pro-
14 vide the care to the participant or bene-
15 ficiary could reasonably be expected to re-
16 sult in—

17 “(I) placing the health of such
18 participant or beneficiary (or, with re-
19 spect to such a participant or bene-
20 ficiary who is a pregnant woman, the
21 health of the woman or her unborn
22 child) in serious jeopardy;

23 “(II) serious impairment to bod-
24 ily functions; or

“(III) serious dysfunction of any
bodily organ or part; or

“(ii) that immediate provision of the
care is necessary because the participant
or beneficiary has made or is at serious
risk of making an attempt to harm himself
or herself or another individual.

“(I) INITIAL DECISION PERIOD.—The term
‘initial decision period’ means a period of 30
days, or such period as may be prescribed in
regulations of the Secretary.

“(J) INTERNAL REVIEW PERIOD.—The
term ‘internal review period’ means a period of
30 days, or such period as may be prescribed
in regulations of the Secretary.

“(K) ACCELERATED NEED DECISION PE-
RIOD.—The term ‘accelerated need decision pe-
riod’ means a period of 3 days, or such period
as may be prescribed in regulations of the Sec-
retary.

“(L) RECONSIDERATION PERIOD.—The
term ‘reconsideration period’ means a period of
25 days, or such period as may be prescribed
in regulations of the Secretary, except that, in
the case of a decision involving accelerated need

1 medical care, such term means the accelerated
2 need decision period.

3 “(M) FILING COMPLETION DATE.—The
4 term ‘filing completion date’ means, in connec-
5 tion with a group health plan, the date as of
6 which the plan is in receipt of all information
7 reasonably required (in writing or in such other
8 reasonable form as may be specified by the
9 plan) to make an initial coverage decision.

10 “(N) REVIEW FILING DATE.—The term
11 ‘review filing date’ means, in connection with a
12 group health plan, the date as of which the ap-
13 propriate named fiduciary (or the independent
14 medical expert or panel of such experts in the
15 case of a review under paragraph (4)) is in re-
16 ceipt of all information reasonably required (in
17 writing or in such other reasonable form as may
18 be specified by the plan) to make a decision to
19 affirm, modify, or reverse a coverage decision.

20 “(O) MEDICAL CARE.—The term ‘medical
21 care’ has the meaning provided such term by
22 section 733(a)(2).

23 “(P) HEALTH INSURANCE COVERAGE.—
24 The term ‘health insurance coverage’ has the

1 meaning provided such term by section
2 733(b)(1).

3 “(Q) HEALTH INSURANCE ISSUER.—The
4 term ‘health insurance issuer’ has the meaning
5 provided such term by section 733(b)(2).

6 “(R) WRITTEN OR IN WRITING.—

7 “(i) IN GENERAL.—A request or deci-
8 sion shall be deemed to be ‘written’ or ‘in
9 writing’ if such request or decision is pre-
10 sented in a generally recognized printable
11 or electronic format. The Secretary may by
12 regulation provide for presentation of in-
13 formation otherwise required to be in writ-
14 ten form in such other forms as may be
15 appropriate under the circumstances.

16 “(ii) MEDICAL APPROPRIATENESS OR
17 INVESTIGATIONAL ITEMS OR EXPERI-
18 MENTAL TREATMENT DETERMINATIONS.—

19 For purposes of this subparagraph, in the
20 case of a request for advance determina-
21 tion of coverage, a request for expedited
22 advance determination of coverage, a re-
23 quest for required determination of medical
24 necessity, or a request for expedited re-
25 quired determination of medical necessity,

1 if the decision on such request is conveyed
2 to the provider of medical care or to the
3 participant or beneficiary by means of tele-
4 phonic or other electronic communications,
5 such decision shall be treated as a written
6 decision.

7 “(S) INCLUDED GROUP HEALTH PLAN
8 BENEFIT.—The term ‘included group health
9 plan benefit’ means a benefit under a group
10 health plan which is not an excepted benefit (as
11 defined in section 733(c)).”.

12 (b) CIVIL PENALTIES.—

13 (1) IN GENERAL.—Section 502(c) of such Act
14 (29 U.S.C. 1132(c)) is amended by redesignating
15 paragraphs (6) and (7) as paragraphs (7) and (8),
16 respectively, and by inserting after paragraph (5)
17 the following new paragraph:

18 “(6)(A)(i) In the case of any failure to timely provide
19 an included group health plan benefit (as defined in sec-
20 tion 503(b)(10)(S)) to a participant or beneficiary, which
21 occurs after the issuance of, and in violation of, a final
22 decision rendered upon completion of external review
23 (under section 503(b)(4)) of an adverse coverage decision
24 by the plan relating to such benefit, any person acting in
25 the capacity of a fiduciary of the plan so as to cause such

1 failure may, in the court's discretion, be liable to the ag-
2 grieved participant or beneficiary for a civil penalty.

3 “(ii) Except as provided in clause (iii), such civil pen-
4 alty shall be in an amount of up to \$1,000 a day from
5 the date that occurs on or after the date of the issuance
6 of the decision under section 503(b)(4) and upon which
7 the plan otherwise could have been reasonably expected
8 to commence compliance with the decision until the date
9 the failure to provide the benefit is corrected.

10 “(iii) In any case in which it is proven by clear and
11 convincing evidence that the person referred to in clause
12 (i) acted willfully and in bad faith, the daily penalty under
13 clause (ii) shall be increased to an amount of up to \$5,000
14 a day.

15 “(iv) In any case in which it is further proven by clear
16 and convincing evidence that—

17 “(I) the plan is not in full compliance with the
18 decision of the independent medical expert (or panel
19 of such experts) under section 503(b)(4)(E)) within
20 the appropriate period specified in such decision,
21 and

22 “(II) the failure to be in full compliance was
23 caused by the plan or by a health insurance issuer
24 offering health insurance coverage in connection
25 with the plan,

1 the plan shall pay the cost of all medical care which was
2 not provided by reason of such failure to fully comply and
3 which is otherwise obtained by the participant or bene-
4 ficiary from any provider.

5 “(B) For purposes of subparagraph (A), the plan,
6 and any health insurance issuer offering health insurance
7 coverage in connection with the plan, shall be deemed to
8 be in compliance with any decision of an independent med-
9 ical expert (or panel of such experts) under section
10 503(b)(4) with respect to any participant or beneficiary
11 upon transmission to such entity (or panel) and to such
12 participant or beneficiary by the plan or issuer of timely
13 notice of an authorization of coverage by the plan or issuer
14 which is consistent with such decision.

15 “(C) In any action commenced under subsection (a)
16 by a participant or beneficiary with respect to an included
17 group health plan benefit in which the plaintiff alleges that
18 a person, in the capacity of a fiduciary and in violation
19 of the terms of the plan or this title, has taken an action
20 resulting in an adverse coverage decision in violation of
21 the terms of the plan, or has failed to take an action for
22 which such person is responsible under the plan and which
23 is necessary under the plan for a favorable coverage deci-
24 sion, upon finding in favor of the plaintiff, if such action
25 was commenced after a final decision of the plan upon

1 review which included a review under section 503(b)(4)
2 or such action was commenced under subsection (b)(4) of
3 this section, the court shall cause to be served on the de-
4 fendant an order requiring the defendant—

5 “(i) to cease and desist from the alleged action
6 or failure to act; and

7 “(ii) to pay to the plaintiff a reasonable attor-
8 ney’s fee and other reasonable costs relating to the
9 prosecution of the action on the charges on which
10 the plaintiff prevails.

11 The remedies provided under this subparagraph shall be
12 in addition to remedies otherwise provided under this sec-
13 tion.

14 “(D)(i) The Secretary may assess a civil penalty
15 against a person acting in the capacity of a fiduciary of
16 one or more group health plans (as defined in section
17 503(b)(9)) for—

18 “(I) any pattern or practice of repeated adverse
19 coverage decisions in connection with included group
20 health plan benefits in violation of the terms of the
21 plan or plans or this title; or

22 “(II) any pattern or practice of repeated viola-
23 tions of the requirements of section 503 in connec-
24 tion with such benefits.

1 Such penalty shall be payable only upon proof by clear
2 and convincing evidence of such pattern or practice.

3 “(ii) Such penalty shall be in an amount not to exceed
4 the lesser of—

5 “(I) 5 percent of the aggregate value of benefits
6 shown by the Secretary to have not been provided,
7 or unlawfully delayed in violation of section 503,
8 under such pattern or practice; or

9 “(II) \$100,000.

10 “(iii) Any person acting in the capacity of a fiduciary
11 of a group health plan or plans who has engaged in any
12 such pattern or practice in connection with included group
13 health plan benefits, upon the petition of the Secretary,
14 may be removed by the court from that position, and from
15 any other involvement, with respect to such plan or plans,
16 and may be precluded from returning to any such position
17 or involvement for a period determined by the court.

18 “(E) For purposes of this paragraph, the term ‘in-
19 cluded group health plan benefit’ has the meaning pro-
20 vided in section 503(b)(10)(S).

21 “(F) The preceding provisions of this paragraph shall
22 not apply with respect to employee benefit plans that are
23 not group health plans or with respect to benefits that are
24 not included group health plan benefits (as defined in
25 paragraph (10)(S)).”.

1 (2) CONFORMING AMENDMENT.—Section
2 502(a)(6) of such Act (29 U.S.C. 1132(a)(6)) is
3 amended by striking “, or (6)” and inserting “, (6),
4 or (7)”.

5 (c) EXPEDITED COURT REVIEW.—Section 502 of
6 such Act (29 U.S.C. 1132) is amended—

7 (1) in subsection (a)(8), by striking “or” at the
8 end;

9 (2) in subsection (a)(9), by striking the period
10 and inserting “; or”;

11 (3) by adding at the end of subsection (a) the
12 following new paragraph:

13 “(10) by a participant or beneficiary for appropriate
14 relief under subsection (b)(4).”.

15 (4) by adding at the end of subsection (b) the
16 following new paragraph:

17 “(4) In any case in which exhaustion of administra-
18 tive remedies in accordance with paragraph (2)(A)(ii) or
19 (2)(B)(ii) of section 503(b) otherwise necessary for an ac-
20 tion for relief under paragraph (1)(B) or (3) of subsection
21 (a) has not been obtained and it is demonstrated to the
22 court by means of certification by an appropriate physi-
23 cian that such exhaustion is not reasonably attainable
24 under the facts and circumstances without undue risk of
25 irreparable harm to the health of the participant or bene-

1 ficiary, a civil action may be brought by a participant or
2 beneficiary to obtain appropriate equitable relief. Any de-
3 terminations made under paragraph (2)(A)(ii) or
4 (2)(B)(ii) of section 503(b) made while an action under
5 this paragraph is pending shall be given due consideration
6 by the court in any such action.”.

7 (d) ATTORNEY’S FEES.—Section 502(g) of such Act
8 (29 U.S.C. 1132(g)) is amended—

9 (1) in paragraph (1), by striking “paragraph
10 (2)” and inserting “paragraph (2) or (3))”; and

11 (2) by adding at the end the following new
12 paragraph:

13 “(3) In any action under this title by a participant
14 or beneficiary in connection with an included group health
15 plan benefit (as defined in section 503(b)(10)(S)) in which
16 judgment in favor of the participant or beneficiary is
17 awarded, the court shall allow a reasonable attorney’s fee
18 and costs of action to the participant or beneficiary.”.

19 (e) STANDARD OF REVIEW UNAFFECTED.—The
20 standard of review under section 502 of the Employee Re-
21 tirement Income Security Act of 1974 (as amended by this
22 section) shall continue on and after the date of the enact-
23 ment of this Act to be the standard of review which was
24 applicable under such section as of immediately before
25 such date.

1 (f) CONCURRENT JURISDICTION.—Section 502(e)(1)
2 of such Act (29 U.S.C. 1132(e)(1)) is amended—

3 (1) in the first sentence, by striking “under
4 subsection (a)(1)(B) of this section” and inserting
5 “under subsection (a)(1)(A) for relief under sub-
6 section (c)(6), under subsection (a)(1)(B), and
7 under subsection (b)(4)”; and

8 (2) in the last sentence, by striking “of actions
9 under paragraphs (1)(B) and (7) of subsection (a)
10 of this section” and inserting “of actions under
11 paragraph (1)(A) of subsection (a) for relief under
12 subsection (c)(6) and of actions under paragraphs
13 (1)(B) and (7) of subsection (a) and paragraph (4)
14 of subsection (b)”.

15 **SEC. 122. SPECIAL RULE FOR ACCESS TO SPECIALTY CARE.**

16 Section 503(b) of such Act (as added by the pre-
17 ceding provisions of this subtitle) is amended by adding
18 at the end the following new paragraph:

19 “(11) SPECIAL RULE FOR ACCESS TO SPE-
20 CIALTY CARE.—

21 “(A) IN GENERAL.—In the case of a re-
22 quest for advance determination of coverage
23 consisting of a request by a physician for a de-
24 termination of coverage of the services of a spe-
25 cialist with respect to any condition, if coverage

1 of the services of such specialist for such condi-
2 tion is otherwise provided under the plan, the
3 initial coverage decision referred to in subpara-
4 graph (A)(i) or (B)(i) of paragraph (2) shall be
5 issued within the accelerated need decision pe-
6 riod.

7 “(B) SPECIALIST.—For purposes of this
8 paragraph, the term ‘specialist’ means, with re-
9 spect to a condition, a physician who has a high
10 level of expertise through appropriate training
11 and experience (including, in the case of a pa-
12 tient who is a child, appropriate pediatric exper-
13 tise) to treat the condition.”.

14 **SEC. 123. REQUIREMENTS FOR TREATMENT OF PRESCRIP-**
15 **TION DRUGS AND MEDICAL DEVICES AS EX-**
16 **PERIMENTAL OR INVESTIGATIONAL.**

17 Section 609 of the Employee Retirement Income Se-
18 curity Act of 1974 (29 U.S.C. 1169) is amended—

19 (1) by redesignating subsection (e) as sub-
20 section (f); and

21 (2) by inserting after subsection (d) the fol-
22 lowing new subsection:

23 “(e) REQUIREMENTS FOR TREATMENT OF PRESCRIP-
24 TION DRUGS AND MEDICAL DEVICES AS EXPERIMENTAL
25 OR INVESTIGATIONAL.—

1 “(1) IN GENERAL.—No use of a prescription
2 drug or medical device shall be considered experi-
3 mental or investigational in connection with a group
4 health plan if such use is included in the labeling au-
5 thorized by the Food and Drug Administration
6 under section 505, 513, or 515 of the Federal Food,
7 Drug, and Cosmetic Act or under section 351 of the
8 Public Health Service Act, unless clinical benefit has
9 not been adequately demonstrated based on analysis
10 of reliable authoritative scientific evidence.

11 “(2) CONSTRUCTION.—Nothing in this sub-
12 section shall be construed as—

13 “(A) requiring a group health plan to pro-
14 vide any coverage of prescription drugs or med-
15 ical devices, or

16 “(B) precluding a group health plan from
17 considering medical devices cleared through pre-
18 market notification under section 510(k) of the
19 Federal Food, Drug, and Cosmetic Act as in-
20 vestigational.

21 “(3) DEFINITIONS.—For purposes of this
22 subsection—

23 “(A) The term ‘group health plan’ shall
24 have the meaning provided such term under
25 such section 733.

“(B) The term ‘clinical benefit’ means improvement in net health outcome (including but not limited to length of life or ability to function) or in any objectively measurable criterion that is reasonably likely to predict clinical benefit to an extent at least equivalent to the extent that is achievable under the usual conditions of medical practice under established alternatives.

“(C) The term ‘reliable authoritative evidence’ means well-designed and well-conducted investigations published in peer-reviewed scientific journals.”.

SEC. 124. PROTECTION FOR CERTAIN INFORMATION DEVELOPED TO REDUCE MORTALITY OR MORBIDITY OR FOR IMPROVING PATIENT CARE AND SAFETY.

(a) PROTECTION OF CERTAIN INFORMATION.—Notwithstanding any other provision of Federal or State law, health care response information shall be exempt from any disclosure requirement (regardless of whether the requirement relates to subpoenas, discovery, introduction of evidence, testimony, or any other form of disclosure), in connection with a civil or administrative proceeding under Federal or State law, to the same extent as information

1 developed by a health care provider with respect to any
2 of the following:

3 (1) Peer review.

4 (2) Utilization review.

5 (3) Quality management or improvement.

6 (4) Quality control.

7 (5) Risk management.

8 (6) Internal review for purposes of reducing
9 mortality, morbidity, or for improving patient care
10 or safety.

11 (b) NO WAIVER OF PROTECTION THROUGH INTER-
12 ACTION WITH ACCREDITING BODY.—Notwithstanding
13 any other provision of Federal or State law, the protection
14 of health care response information from disclosure pro-
15 vided under subsection (a) shall not be deemed to be modi-
16 fied or in any way waived by—

17 (1) the development of such information in con-
18 nection with a request or requirement of an accred-
19 iting body; or

20 (2) the transfer of such information to an ac-
21 crediting body.

22 (c) DEFINITIONS.—For purposes of this section:

23 (1) The term “accrediting body” means a na-
24 tional, not-for-profit organization that—

25 (A) accredits health care providers; and

1 (B) is recognized as an accrediting body by
2 statute or by a Federal or State agency that
3 regulates health care providers.

4 (2) The term “health care provider” has the
5 meaning given such term in section 1188 of the So-
6 cial Security Act (as added by section 5001 of this
7 Act).

8 (3) The term “health care response informa-
9 tion” means information (including any data, report,
10 record, memorandum, analysis, statement, or other
11 communication) developed by, or on behalf of, a
12 health care provider in response to a serious, ad-
13 verse, patient-related event—

14 (A) during the course of analyzing or
15 studying the event and its causes; and

16 (B) for purposes of—

17 (i) reducing mortality or morbidity; or

18 (ii) improving patient care or safety
19 (including the provider’s notification to an
20 accrediting body and the provider’s plans
21 of action in response to such event).

22 (5) The term “State” includes the District of
23 Columbia, Puerto Rico, the Virgin Islands, Guam,
24 American Samoa, and the Northern Mariana Is-
25 lands.

1 **SEC. 125. EFFECTIVE DATE.**

2 (a) IN GENERAL.—The amendments made by sec-
3 tions 801 and 802 shall apply with respect to grievances
4 arising in plan years beginning on or after January 1 of
5 the second calendar year following 12 months after the
6 date the Secretary of Labor issues all regulations nec-
7 essary to carry out amendments made by this title. The
8 amendments made by section 803 shall take effect on such
9 January 1.

10 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
11 enforcement action shall be taken, pursuant to the amend-
12 ments made by this title, against a group health plan or
13 health insurance issuer with respect to a violation of a re-
14 quirement imposed by such amendments before the date
15 of issuance of final regulations issued in connection with
16 such requirement, if the plan or issuer has sought to com-
17 ply in good faith with such requirement.

18 (c) COLLECTIVE BARGAINING AGREEMENTS.—Any
19 plan amendment made pursuant to a collective bargaining
20 agreement relating to the plan which amends the plan
21 solely to conform to any requirement added by this title
22 shall not be treated as a termination of such collective bar-
23 gaining agreement.

1 **Subtitle D—Small Business Access**
2 **and Choice for Entrepreneurs**

3 **SEC. 131. RULES GOVERNING ASSOCIATION HEALTH**
4 **PLANS.**

5 (a) IN GENERAL.—Subtitle B of title I of the Em-
6 ployee Retirement Income Security Act of 1974 is amend-
7 ed by adding after part 7 the following new part:

8 “PART 8—RULES GOVERNING ASSOCIATION HEALTH
9 PLANS

10 **“SEC. 801. ASSOCIATION HEALTH PLANS.**

11 “(a) IN GENERAL.—For purposes of this part, the
12 term ‘association health plan’ means a group health
13 plan—

14 “(1) whose sponsor is (or is deemed under this
15 part to be) described in subsection (b); and

16 “(2) under which at least two options of health
17 insurance coverage offered by a health insurance
18 issuer (which may include, among other options,
19 managed care options, point of service options, and
20 preferred provider options) is provided to partici-
21 pants and beneficiaries, unless, for any plan year,
22 such coverage remains unavailable to the plan de-
23 spite good faith efforts exercised by the plan to se-
24 cure such coverage.

1 “(b) SPONSORSHIP.—The sponsor of a group health
2 plan is described in this subsection if such sponsor—

3 “(1) is organized and maintained in good faith,
4 with a constitution and bylaws specifically stating its
5 purpose and providing for periodic meetings on at
6 least an annual basis, as a bona fide trade associa-
7 tion, a bona fide industry association (including a
8 rural electric cooperative association or a rural tele-
9 phone cooperative association), a bona fide profes-
10 sional association, or a bona fide chamber of com-
11 merce (or similar bona fide business association, in-
12 cluding a corporation or similar organization that
13 operates on a cooperative basis (within the meaning
14 of section 1381 of the Internal Revenue Code of
15 1986)), for substantial purposes other than that of
16 obtaining or providing medical care;

17 “(2) is established as a permanent entity which
18 receives the active support of its members and col-
19 lects from its members on a periodic basis dues or
20 payments necessary to maintain eligibility for mem-
21 bership in the sponsor; and

22 “(3) does not condition membership, such dues
23 or payments, or coverage under the plan on the
24 basis of health status-related factors with respect to
25 the employees of its members (or affiliated mem-

1 bers), or the dependents of such employees, and does
2 not condition such dues or payments on the basis of
3 group health plan participation.

4 Any sponsor consisting of an association of entities which
5 meet the requirements of paragraphs (1), (2), and (3)
6 shall be deemed to be a sponsor described in this sub-
7 section.

8 **“SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH**
9 **PLANS.**

10 “(a) IN GENERAL.—The applicable authority shall
11 prescribe by regulation, through negotiated rulemaking, a
12 procedure under which, subject to subsection (b), the ap-
13 plicable authority shall certify association health plans
14 which apply for certification as meeting the requirements
15 of this part.

16 “(b) STANDARDS.—Under the procedure prescribed
17 pursuant to subsection (a), in the case of an association
18 health plan that provides at least one benefit option which
19 does not consist of health insurance coverage, the applica-
20 ble authority shall certify such plan as meeting the re-
21 quirements of this part only if the applicable authority is
22 satisfied that—

23 “(1) such certification—

24 “(A) is administratively feasible;

“(B) is not adverse to the interests of the individuals covered under the plan; and

“(C) is protective of the rights and benefits of the individuals covered under the plan; and

“(2) the applicable requirements of this part are met (or, upon the date on which the plan is to commence operations, will be met) with respect to the plan.

“(c) REQUIREMENTS APPLICABLE TO CERTIFIED PLANS.—An association health plan with respect to which certification under this part is in effect shall meet the applicable requirements of this part, effective on the date of certification (or, if later, on the date on which the plan is to commence operations).

“(d) REQUIREMENTS FOR CONTINUED CERTIFICATION.—The applicable authority may provide by regulation, through negotiated rulemaking, for continued certification of association health plans under this part.

“(e) CLASS CERTIFICATION FOR FULLY INSURED PLANS.—The applicable authority shall establish a class certification procedure for association health plans under which all benefits consist of health insurance coverage. Under such procedure, the applicable authority shall provide for the granting of certification under this part to the plans in each class of such association health plans

1 upon appropriate filing under such procedure in connec-
2 tion with plans in such class and payment of the pre-
3 scribed fee under section 807(a).

4 “(f) CERTIFICATION OF SELF-INSURED ASSOCIATION
5 HEALTH PLANS.—An association health plan which offers
6 one or more benefit options which do not consist of health
7 insurance coverage may be certified under this part only
8 if such plan consists of any of the following:

9 “(1) a plan which offered such coverage on the
10 date of the enactment of the Comprehensive Access
11 and Responsibility in Health Care Act of 1999,

12 “(2) a plan under which the sponsor does not
13 restrict membership to one or more trades and busi-
14 nesses or industries and whose eligible participating
15 employers represent a broad cross-section of trades
16 and businesses or industries, or

17 “(3) a plan whose eligible participating employ-
18 ers represent one or more trades or businesses, or
19 one or more industries, which have been indicated as
20 having average or above-average health insurance
21 risk or health claims experience by reason of State
22 rate filings, denials of coverage, proposed premium
23 rate levels, and other means demonstrated by such
24 plan in accordance with regulations which the Sec-
25 retary shall prescribe through negotiated rule-

making, including (but not limited to) the following:
agriculture; automobile dealerships; barbering and
cosmetology; child care; construction; dance, theatrical, and orchestra productions; disinfecting and
pest control; eating and drinking establishments;
fishing; hospitals; labor organizations; logging; manufacturing (metals); mining; medical and dental
practices; medical laboratories; sanitary services;
transportation (local and freight); and warehousing.

**“SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND
BOARDS OF TRUSTEES.**

“(a) SPONSOR.—The requirements of this subsection are met with respect to an association health plan if the sponsor has met (or is deemed under this part to have met) the requirements of section 801(b) for a continuous period of not less than 3 years ending with the date of the application for certification under this part.

“(b) BOARD OF TRUSTEES.—The requirements of this subsection are met with respect to an association health plan if the following requirements are met:

“(1) FISCAL CONTROL.—The plan is operated, pursuant to a trust agreement, by a board of trustees which has complete fiscal control over the plan and which is responsible for all operations of the plan.

1 “(2) RULES OF OPERATION AND FINANCIAL
2 CONTROLS.—The board of trustees has in effect
3 rules of operation and financial controls, based on a
4 3-year plan of operation, adequate to carry out the
5 terms of the plan and to meet all requirements of
6 this title applicable to the plan.

7 “(3) RULES GOVERNING RELATIONSHIP TO
8 PARTICIPATING EMPLOYERS AND TO CONTRAC-
9 TORS.—

10 “(A) IN GENERAL.—Except as provided in
11 subparagraphs (B) and (C), the members of the
12 board of trustees are individuals selected from
13 individuals who are the owners, officers, direc-
14 tors, or employees of the participating employ-
15 ers or who are partners in the participating em-
16 ployers and actively participate in the business.

17 “(B) LIMITATION.—

18 “(i) GENERAL RULE.—Except as pro-
19 vided in clauses (ii) and (iii), no such
20 member is an owner, officer, director, or
21 employee of, or partner in, a contract ad-
22 ministrator or other service provider to the
23 plan.

24 “(ii) LIMITED EXCEPTION FOR PRO-
25 VIDERS OF SERVICES SOLELY ON BEHALF

1 OF THE SPONSOR.—Officers or employees
2 of a sponsor which is a service provider
3 (other than a contract administrator) to
4 the plan may be members of the board if
5 they constitute not more than 25 percent
6 of the membership of the board and they
7 do not provide services to the plan other
8 than on behalf of the sponsor.

9 “(iii) TREATMENT OF PROVIDERS OF
10 MEDICAL CARE.—In the case of a sponsor
11 which is an association whose membership
12 consists primarily of providers of medical
13 care, clause (i) shall not apply in the case
14 of any service provider described in sub-
15 paragraph (A) who is a provider of medical
16 care under the plan.

17 “(C) CERTAIN PLANS EXCLUDED.—Sub-
18 paragraph (A) shall not apply to an association
19 health plan which is in existence on the date of
20 the enactment of the Comprehensive Access and
21 Responsibility in Health Care Act of 1999.

22 “(D) SOLE AUTHORITY.—The board has
23 sole authority under the plan to approve appli-
24 cations for participation in the plan and to con-

1 tract with a service provider to administer the
2 day-to-day affairs of the plan.

3 “(c) TREATMENT OF FRANCHISE NETWORKS.—In
4 the case of a group health plan which is established and
5 maintained by a franchiser for a franchise network con-
6 sisting of its franchisees—

7 “(1) the requirements of subsection (a) and sec-
8 tion 801(a)(1) shall be deemed met if such require-
9 ments would otherwise be met if the franchiser were
10 deemed to be the sponsor referred to in section
11 801(b), such network were deemed to be an associa-
12 tion described in section 801(b), and each franchisee
13 were deemed to be a member (of the association and
14 the sponsor) referred to in section 801(b); and

15 “(2) the requirements of section 804(a)(1) shall
16 be deemed met.

17 The Secretary may by regulation, through negotiated rule-
18 making, define for purposes of this subsection the terms
19 ‘franchiser’, ‘franchise network’, and ‘franchisee’.

20 “(d) CERTAIN COLLECTIVELY BARGAINED PLANS.—

21 “(1) IN GENERAL.—In the case of a group
22 health plan described in paragraph (2)—

23 “(A) the requirements of subsection (a)
24 and section 801(a)(1) shall be deemed met;

“(B) the joint board of trustees shall be deemed a board of trustees with respect to which the requirements of subsection (b) are met; and

“(C) the requirements of section 804 shall be deemed met.

“(2) REQUIREMENTS.—A group health plan is described in this paragraph if—

“(A) the plan is a multiemployer plan; or

“(B) the plan is in existence on April 1, 1997, and would be described in section 3(40)(A)(i) but solely for the failure to meet the requirements of section 3(40)(C)(ii).

“SEC. 804. PARTICIPATION AND COVERAGE REQUIREMENTS.

“(a) COVERED EMPLOYERS AND INDIVIDUALS.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan—

“(1) each participating employer must be—

“(A) a member of the sponsor,

“(B) the sponsor, or

“(C) an affiliated member of the sponsor with respect to which the requirements of subsection (b) are met,

1 except that, in the case of a sponsor which is a pro-
2 fessional association or other individual-based asso-
3 ciation, if at least one of the officers, directors, or
4 employees of an employer, or at least one of the in-
5 dividuals who are partners in an employer and who
6 actively participates in the business, is a member or
7 such an affiliated member of the sponsor, partici-
8 pating employers may also include such employer;
9 and

10 “(2) all individuals commencing coverage under
11 the plan after certification under this part must
12 be—

13 “(A) active or retired owners (including
14 self-employed individuals), officers, directors, or
15 employees of, or partners in, participating em-
16 ployers; or

17 “(B) the beneficiaries of individuals de-
18 scribed in subparagraph (A).

19 “(b) COVERAGE OF PREVIOUSLY UNINSURED EM-
20 PLOYEES.—In the case of an association health plan in
21 existence on the date of the enactment of the Comprehen-
22 sive Access and Responsibility in Health Care Act of 1999,
23 an affiliated member of the sponsor of the plan may be
24 offered coverage under the plan as a participating em-
25 ployer only if—

“(1) the affiliated member was an affiliated member on the date of certification under this part; or

“(2) during the 12-month period preceding the date of the offering of such coverage, the affiliated member has not maintained or contributed to a group health plan with respect to any of its employees who would otherwise be eligible to participate in such association health plan.

“(c) INDIVIDUAL MARKET UNAFFECTED.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan, no participating employer may provide health insurance coverage in the individual market for any employee not covered under the plan which is similar to the coverage contemporaneously provided to employees of the employer under the plan, if such exclusion of the employee from coverage under the plan is based on a health status-related factor with respect to the employee and such employee would, but for such exclusion on such basis, be eligible for coverage under the plan.

“(d) PROHIBITION OF DISCRIMINATION AGAINST EMPLOYERS AND EMPLOYEES ELIGIBLE TO PARTICIPATE.—The requirements of this subsection are met with respect to an association health plan if—

1 “(1) under the terms of the plan, all employers
2 meeting the preceding requirements of this section
3 are eligible to qualify as participating employers for
4 all geographically available coverage options, unless,
5 in the case of any such employer, participation or
6 contribution requirements of the type referred to in
7 section 2711 of the Public Health Service Act are
8 not met;

9 “(2) all such coverage options under the plan
10 are actively marketed to such participating employ-
11 ers; and

12 “(3) the applicable requirements of sections
13 701, 702, and 703 are met with respect to the plan.

14 **“SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN**
15 **DOCUMENTS, CONTRIBUTION RATES, AND**
16 **BENEFIT OPTIONS.**

17 “(a) IN GENERAL.—The requirements of this section
18 are met with respect to an association health plan if the
19 following requirements are met:

20 “(1) CONTENTS OF GOVERNING INSTRU-
21 MENTS.—The instruments governing the plan in-
22 clude a written instrument, meeting the require-
23 ments of an instrument required under section
24 402(a)(1), which—

1 “(A) provides that the board of trustees
2 serves as the named fiduciary required for plans
3 under section 402(a)(1) and serves in the ca-
4 pacity of a plan administrator (referred to in
5 section 3(16)(A));

6 “(B) provides that the sponsor of the plan
7 is to serve as plan sponsor (referred to in sec-
8 tion 3(16)(B)); and

9 “(C) incorporates the requirements of sec-
10 tion 806.

11 “(2) CONTRIBUTION RATES MUST BE NON-
12 DISCRIMINATORY.—

13 “(A) The contribution rates for any par-
14 ticipating small employer do not vary on the
15 basis of the claims experience of such employer
16 and do not vary on the basis of the type of
17 business or industry in which such employer is
18 engaged.

19 “(B) Nothing in this title or any other pro-
20 vision of law shall be construed to preclude an
21 association health plan, or a health insurance
22 issuer offering health insurance coverage in
23 connection with an association health plan,
24 from—

1 “(i) setting contribution rates based
2 on the claims experience of the plan; or

3 “(ii) varying contribution rates for
4 small employers in a State to the extent
5 that such rates could vary using the same
6 methodology employed in such State for
7 regulating premium rates in the small
8 group market with respect to health insur-
9 ance coverage offered in connection with
10 bona fide associations (within the meaning
11 of section 2791(d)(3) of the Public Health
12 Service Act),

13 subject to the requirements of section 702(b)
14 relating to contribution rates.

15 “(3) FLOOR FOR NUMBER OF COVERED INDIVIDUALS WITH RESPECT TO CERTAIN PLANS.—If
16 any benefit option under the plan does not consist
17 of health insurance coverage, the plan has as of the
18 beginning of the plan year not fewer than 1,000 par-
19 ticipants and beneficiaries.

21 “(4) MARKETING REQUIREMENTS.—

22 “(A) IN GENERAL.—If a benefit option
23 which consists of health insurance coverage is
24 offered under the plan, State-licensed insurance
25 agents shall be used to distribute to small em-

1 employers coverage which does not consist of
2 health insurance coverage in a manner com-
3 parable to the manner in which such agents are
4 used to distribute health insurance coverage.

5 “(B) STATE-LICENSED INSURANCE
6 AGENTS.—For purposes of subparagraph (A),
7 the term ‘State-licensed insurance agents’
8 means one or more agents who are licensed in
9 a State and are subject to the laws of such
10 State relating to licensure, qualification, test-
11 ing, examination, and continuing education of
12 persons authorized to offer, sell, or solicit
13 health insurance coverage in such State.

14 “(5) REGULATORY REQUIREMENTS.—Such
15 other requirements as the applicable authority deter-
16 mines are necessary to carry out the purposes of this
17 part, which shall be prescribed by the applicable au-
18 thority by regulation through negotiated rulemaking.

19 “(b) ABILITY OF ASSOCIATION HEALTH PLANS TO
20 DESIGN BENEFIT OPTIONS.—Subject to section 514(d),
21 nothing in this part or any provision of State law (as de-
22 fined in section 514(c)(1)) shall be construed to preclude
23 an association health plan, or a health insurance issuer
24 offering health insurance coverage in connection with an
25 association health plan, from exercising its sole discretion

1 in selecting the specific items and services consisting of
2 medical care to be included as benefits under such plan
3 or coverage, except (subject to section 514) in the case
4 of any law to the extent that it (1) prohibits an exclusion
5 of a specific disease from such coverage, or (2) is not pre-
6 empted under section 731(a)(1) with respect to matters
7 governed by section 711 or 712.

8 **“SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS**
9 **FOR SOLVENCY FOR PLANS PROVIDING**
10 **HEALTH BENEFITS IN ADDITION TO HEALTH**
11 **INSURANCE COVERAGE.**

12 “(a) IN GENERAL.—The requirements of this section
13 are met with respect to an association health plan if—

14 “(1) the benefits under the plan consist solely
15 of health insurance coverage; or

16 “(2) if the plan provides any additional benefit
17 options which do not consist of health insurance cov-
18 erage, the plan—

19 “(A) establishes and maintains reserves
20 with respect to such additional benefit options,
21 in amounts recommended by the qualified actu-
22 ary, consisting of—

23 “(i) a reserve sufficient for unearned
24 contributions;

1 “(ii) a reserve sufficient for benefit li-
2 abilities which have been incurred, which
3 have not been satisfied, and for which risk
4 of loss has not yet been transferred, and
5 for expected administrative costs with re-
6 spect to such benefit liabilities;

7 “(iii) a reserve sufficient for any other
8 obligations of the plan; and

9 “(iv) a reserve sufficient for a margin
10 of error and other fluctuations, taking into
11 account the specific circumstances of the
12 plan; and

13 “(B) establishes and maintains aggregate
14 and specific excess/stop loss insurance and sol-
15 vency indemnification, with respect to such ad-
16 ditional benefit options for which risk of loss
17 has not yet been transferred, as follows:

18 “(i) The plan shall secure aggregate
19 excess/stop loss insurance for the plan
20 with an attachment point which is not
21 greater than 125 percent of expected gross
22 annual claims. The applicable authority
23 may by regulation, through negotiated
24 rulemaking, provide for upward adjust-
25 ments in the amount of such percentage in

1 specified circumstances in which the plan
2 specifically provides for and maintains re-
3 serves in excess of the amounts required
4 under subparagraph (A).

5 “(ii) The plan shall secure specific ex-
6 cess/stop loss insurance for the plan with
7 an attachment point which is at least equal
8 to an amount recommended by the plan’s
9 qualified actuary (but not more than
10 \$175,000). The applicable authority may
11 by regulation, through negotiated rule-
12 making, provide for adjustments in the
13 amount of such insurance in specified cir-
14 cumstances in which the plan specifically
15 provides for and maintains reserves in ex-
16 cess of the amounts required under sub-
17 paragraph (A).

18 “(iii) The plan shall secure indem-
19 nification insurance for any claims which
20 the plan is unable to satisfy by reason of
21 a plan termination.

22 Any regulations prescribed by the applicable authority
23 pursuant to clause (i) or (ii) of subparagraph (B) may
24 allow for such adjustments in the required levels of excess/
25 stop loss insurance as the qualified actuary may rec-

1 commend, taking into account the specific circumstances
2 of the plan.

3 “(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS
4 RESERVES.—In the case of any association health plan de-
5 scribed in subsection (a)(2), the requirements of this sub-
6 section are met if the plan establishes and maintains sur-
7 plus in an amount at least equal to—

8 “(1) \$500,000, or

9 “(2) such greater amount (but not greater than
10 \$2,000,000) as may be set forth in regulations pre-
11 scribed by the applicable authority through nego-
12 tiated rulemaking, based on the level of aggregate
13 and specific excess/stop loss insurance provided with
14 respect to such plan.

15 “(c) ADDITIONAL REQUIREMENTS.—In the case of
16 any association health plan described in subsection (a)(2),
17 the applicable authority may provide such additional re-
18 quirements relating to reserves and excess/stop loss insur-
19 ance as the applicable authority considers appropriate.
20 Such requirements may be provided by regulation, through
21 negotiated rulemaking, with respect to any such plan or
22 any class of such plans.

23 “(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSUR-
24 ANCE.—The applicable authority may provide for adjust-
25 ments to the levels of reserves otherwise required under

1 subsections (a) and (b) with respect to any plan or class
2 of plans to take into account excess/stop loss insurance
3 provided with respect to such plan or plans.

4 “(e) ALTERNATIVE MEANS OF COMPLIANCE.—The
5 applicable authority may permit an association health plan
6 described in subsection (a)(2) to substitute, for all or part
7 of the requirements of this section (except subsection
8 (a)(2)(B)(iii)), such security, guarantee, hold-harmless ar-
9 rangement, or other financial arrangement as the applica-
10 ble authority determines to be adequate to enable the plan
11 to fully meet all its financial obligations on a timely basis
12 and is otherwise no less protective of the interests of par-
13 ticipants and beneficiaries than the requirements for
14 which it is substituted. The applicable authority may take
15 into account, for purposes of this subsection, evidence pro-
16 vided by the plan or sponsor which demonstrates an as-
17 sumption of liability with respect to the plan. Such evi-
18 dence may be in the form of a contract of indemnification,
19 lien, bonding, insurance, letter of credit, recourse under
20 applicable terms of the plan in the form of assessments
21 of participating employers, security, or other financial ar-
22 rangement.

23 “(f) MEASURES TO ENSURE CONTINUED PAYMENT
24 OF BENEFITS BY CERTAIN PLANS IN DISTRESS.—

1 “(1) PAYMENTS BY CERTAIN PLANS TO ASSO-
2 CIATION HEALTH PLAN FUND.—

3 “(A) IN GENERAL.—In the case of an as-
4 sociation health plan described in subsection
5 (a)(2), the requirements of this subsection are
6 met if the plan makes payments into the Asso-
7 ciation Health Plan Fund under this subpara-
8 graph when they are due. Such payments shall
9 consist of annual payments in the amount of
10 \$5,000, and, in addition to such annual pay-
11 ments, such supplemental payments as the Sec-
12 retary may determine to be necessary under
13 paragraph (2). Payments under this paragraph
14 are payable to the Fund at the time determined
15 by the Secretary. Initial payments are due in
16 advance of certification under this part. Pay-
17 ments shall continue to accrue until a plan’s as-
18 sets are distributed pursuant to a termination
19 procedure.

20 “(B) PENALTIES FOR FAILURE TO MAKE
21 PAYMENTS.—If any payment is not made by a
22 plan when it is due, a late payment charge of
23 not more than 100 percent of the payment
24 which was not timely paid shall be payable by
25 the plan to the Fund.

1 “(C) CONTINUED DUTY OF THE SEC-
2 RETARY.—The Secretary shall not cease to
3 carry out the provisions of paragraph (2) on ac-
4 count of the failure of a plan to pay any pay-
5 ment when due.

6 “(2) PAYMENTS BY SECRETARY TO CONTINUE
7 EXCESS/STOP LOSS INSURANCE COVERAGE AND IN-
8 DEMNIFICATION INSURANCE COVERAGE FOR CER-
9 TAIN PLANS.—In any case in which the applicable
10 authority determines that there is, or that there is
11 reason to believe that there will be: (A) a failure to
12 take necessary corrective actions under section
13 809(a) with respect to an association health plan de-
14 scribed in subsection (a)(2); or (B) a termination of
15 such a plan under section 809(b) or 810(b)(8) (and,
16 if the applicable authority is not the Secretary, cer-
17 tifies such determination to the Secretary), the Sec-
18 retary shall determine the amounts necessary to
19 make payments to an insurer (designated by the
20 Secretary) to maintain in force excess/stop loss in-
21 surance coverage or indemnification insurance cov-
22 erage for such plan, if the Secretary determines that
23 there is a reasonable expectation that, without such
24 payments, claims would not be satisfied by reason of
25 termination of such coverage. The Secretary shall, to

1 the extent provided in advance in appropriation
2 Acts, pay such amounts so determined to the insurer
3 designated by the Secretary.

4 “(3) ASSOCIATION HEALTH PLAN FUND.—

5 “(A) IN GENERAL.—There is established
6 on the books of the Treasury a fund to be
7 known as the ‘Association Health Plan Fund’.
8 The Fund shall be available for making pay-
9 ments pursuant to paragraph (2). The Fund
10 shall be credited with payments received pursu-
11 ant to paragraph (1)(A), penalties received pur-
12 suant to paragraph (1)(B); and earnings on in-
13 vestments of amounts of the Fund under sub-
14 paragraph (B).

15 “(B) INVESTMENT.—Whenever the Sec-
16 retary determines that the moneys of the fund
17 are in excess of current needs, the Secretary
18 may request the investment of such amounts as
19 the Secretary determines advisable by the Sec-
20 retary of the Treasury in obligations issued or
21 guaranteed by the United States.

22 “(g) EXCESS/STOP LOSS INSURANCE.—For pur-
23 poses of this section—

24 “(1) AGGREGATE EXCESS/STOP LOSS INSUR-
25 ANCE.—The term ‘aggregate excess/stop loss insur-

1 ance' means, in connection with an association
2 health plan, a contract—

3 “(A) under which an insurer (meeting such
4 minimum standards as the applicable authority
5 may prescribe by regulation through negotiated
6 rulemaking) provides for payment to the plan
7 with respect to aggregate claims under the plan
8 in excess of an amount or amounts specified in
9 such contract;

10 “(B) which is guaranteed renewable; and

11 “(C) which allows for payment of pre-
12 miums by any third party on behalf of the in-
13 sured plan.

14 “(2) SPECIFIC EXCESS/STOP LOSS INSUR-
15 ANCE.—The term ‘specific excess/stop loss insur-
16 ance’ means, in connection with an association
17 health plan, a contract—

18 “(A) under which an insurer (meeting such
19 minimum standards as the applicable authority
20 may prescribe by regulation through negotiated
21 rulemaking) provides for payment to the plan
22 with respect to claims under the plan in connec-
23 tion with a covered individual in excess of an
24 amount or amounts specified in such contract
25 in connection with such covered individual;

1 “(B) which is guaranteed renewable; and

2 “(C) which allows for payment of pre-
3 miums by any third party on behalf of the in-
4 sured plan.

5 “(h) INDEMNIFICATION INSURANCE.—For purposes
6 of this section, the term ‘indemnification insurance’
7 means, in connection with an association health plan, a
8 contract—

9 “(1) under which an insurer (meeting such min-
10 imum standards as the applicable authority may pre-
11 scribe through negotiated rulemaking) provides for
12 payment to the plan with respect to claims under the
13 plan which the plan is unable to satisfy by reason
14 of a termination pursuant to section 809(b) (relating
15 to mandatory termination);

16 “(2) which is guaranteed renewable and
17 noncancellable for any reason (except as the applica-
18 ble authority may prescribe by regulation through
19 negotiated rulemaking); and

20 “(3) which allows for payment of premiums by
21 any third party on behalf of the insured plan.

22 “(i) RESERVES.—For purposes of this section, the
23 term ‘reserves’ means, in connection with an association
24 health plan, plan assets which meet the fiduciary stand-
25 ards under part 4 and such additional requirements re-

1 garding liquidity as the applicable authority may prescribe
2 through negotiated rulemaking.

3 “(j) SOLVENCY STANDARDS WORKING GROUP.—

4 “(1) IN GENERAL.—Within 90 days after the
5 date of the enactment of the Comprehensive Access
6 and Responsibility in Health Care Act of 1999, the
7 applicable authority shall establish a Solvency
8 Standards Working Group. In prescribing the initial
9 regulations under this section, the applicable author-
10 ity shall take into account the recommendations of
11 such Working Group.

12 “(2) MEMBERSHIP.—The Working Group shall
13 consist of not more than 15 members appointed by
14 the applicable authority. The applicable authority
15 shall include among persons invited to membership
16 on the Working Group at least one of each of the
17 following:

18 “(A) a representative of the National Asso-
19 ciation of Insurance Commissioners;

20 “(B) a representative of the American
21 Academy of Actuaries;

22 “(C) a representative of the State govern-
23 ments, or their interests;

24 “(D) a representative of existing self-in-
25 sured arrangements, or their interests;

1 “(E) a representative of associations of the
2 type referred to in section 801(b)(1), or their
3 interests; and

4 “(F) a representative of multiemployer
5 plans that are group health plans, or their in-
6 terests.

7 **“SEC. 807. REQUIREMENTS FOR APPLICATION AND RE-**
8 **LATED REQUIREMENTS.**

9 “(a) **FILING FEE.**—Under the procedure prescribed
10 pursuant to section 802(a), an association health plan
11 shall pay to the applicable authority at the time of filing
12 an application for certification under this part a filing fee
13 in the amount of \$5,000, which shall be available in the
14 case of the Secretary, to the extent provided in appropria-
15 tion Acts, for the sole purpose of administering the certifi-
16 cation procedures applicable with respect to association
17 health plans.

18 “(b) **INFORMATION TO BE INCLUDED IN APPLICA-**
19 **TION FOR CERTIFICATION.**—An application for certifi-
20 cation under this part meets the requirements of this sec-
21 tion only if it includes, in a manner and form which shall
22 be prescribed by the applicable authority through nego-
23 tiated rulemaking, at least the following information:

24 “(1) **IDENTIFYING INFORMATION.**—The names
25 and addresses of—

1 “(A) the sponsor; and

2 “(B) the members of the board of trustees
3 of the plan.

4 “(2) STATES IN WHICH PLAN INTENDS TO DO
5 BUSINESS.—The States in which participants and
6 beneficiaries under the plan are to be located and
7 the number of them expected to be located in each
8 such State.

9 “(3) BONDING REQUIREMENTS.—Evidence pro-
10 vided by the board of trustees that the bonding re-
11 quirements of section 412 will be met as of the date
12 of the application or (if later) commencement of op-
13 erations.

14 “(4) PLAN DOCUMENTS.—A copy of the docu-
15 ments governing the plan (including any bylaws and
16 trust agreements), the summary plan description,
17 and other material describing the benefits that will
18 be provided to participants and beneficiaries under
19 the plan.

20 “(5) AGREEMENTS WITH SERVICE PRO-
21 VIDERS.—A copy of any agreements between the
22 plan and contract administrators and other service
23 providers.

24 “(6) FUNDING REPORT.—In the case of asso-
25 ciation health plans providing benefits options in ad-

1 dition to health insurance coverage, a report setting
2 forth information with respect to such additional
3 benefit options determined as of a date within the
4 120-day period ending with the date of the applica-
5 tion, including the following:

6 “(A) RESERVES.—A statement, certified
7 by the board of trustees of the plan, and a
8 statement of actuarial opinion, signed by a
9 qualified actuary, that all applicable require-
10 ments of section 806 are or will be met in ac-
11 cordance with regulations which the applicable
12 authority shall prescribe through negotiated
13 rulemaking.

14 “(B) ADEQUACY OF CONTRIBUTION
15 RATES.—A statement of actuarial opinion,
16 signed by a qualified actuary, which sets forth
17 a description of the extent to which contribution
18 rates are adequate to provide for the payment
19 of all obligations and the maintenance of re-
20 quired reserves under the plan for the 12-
21 month period beginning with such date within
22 such 120-day period, taking into account the
23 expected coverage and experience of the plan. If
24 the contribution rates are not fully adequate,
25 the statement of actuarial opinion shall indicate

1 the extent to which the rates are inadequate
2 and the changes needed to ensure adequacy.

3 “(C) CURRENT AND PROJECTED VALUE OF
4 ASSETS AND LIABILITIES.—A statement of ac-
5 tuarial opinion signed by a qualified actuary,
6 which sets forth the current value of the assets
7 and liabilities accumulated under the plan and
8 a projection of the assets, liabilities, income,
9 and expenses of the plan for the 12-month pe-
10 riod referred to in subparagraph (B). The in-
11 come statement shall identify separately the
12 plan’s administrative expenses and claims.

13 “(D) COSTS OF COVERAGE TO BE
14 CHARGED AND OTHER EXPENSES.—A state-
15 ment of the costs of coverage to be charged, in-
16 cluding an itemization of amounts for adminis-
17 tration, reserves, and other expenses associated
18 with the operation of the plan.

19 “(E) OTHER INFORMATION.—Any other
20 information as may be determined by the appli-
21 cable authority, by regulation through nego-
22 tiated rulemaking, as necessary to carry out the
23 purposes of this part.

24 “(c) FILING NOTICE OF CERTIFICATION WITH
25 STATES.—A certification granted under this part to an

1 association health plan shall not be effective unless written
2 notice of such certification is filed with the applicable
3 State authority of each State in which at least 25 percent
4 of the participants and beneficiaries under the plan are
5 located. For purposes of this subsection, an individual
6 shall be considered to be located in the State in which a
7 known address of such individual is located or in which
8 such individual is employed.

9 “(d) NOTICE OF MATERIAL CHANGES.—In the case
10 of any association health plan certified under this part,
11 descriptions of material changes in any information which
12 was required to be submitted with the application for the
13 certification under this part shall be filed in such form
14 and manner as shall be prescribed by the applicable au-
15 thority by regulation through negotiated rulemaking. The
16 applicable authority may require by regulation, through
17 negotiated rulemaking, prior notice of material changes
18 with respect to specified matters which might serve as the
19 basis for suspension or revocation of the certification.

20 “(e) REPORTING REQUIREMENTS FOR CERTAIN AS-
21 SOCIATION HEALTH PLANS.—An association health plan
22 certified under this part which provides benefit options in
23 addition to health insurance coverage for such plan year
24 shall meet the requirements of section 103 by filing an
25 annual report under such section which shall include infor-

1 mation described in subsection (b)(6) with respect to the
2 plan year and, notwithstanding section 104(a)(1)(A), shall
3 be filed with the applicable authority not later than 90
4 days after the close of the plan year (or on such later date
5 as may be prescribed by the applicable authority). The ap-
6 plicable authority may require by regulation through nego-
7 tiated rulemaking such interim reports as it considers ap-
8 propriate.

9 “(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The
10 board of trustees of each association health plan which
11 provides benefits options in addition to health insurance
12 coverage and which is applying for certification under this
13 part or is certified under this part shall engage, on behalf
14 of all participants and beneficiaries, a qualified actuary
15 who shall be responsible for the preparation of the mate-
16 rials comprising information necessary to be submitted by
17 a qualified actuary under this part. The qualified actuary
18 shall utilize such assumptions and techniques as are nec-
19 essary to enable such actuary to form an opinion as to
20 whether the contents of the matters reported under this
21 part—

22 “(1) are in the aggregate reasonably related to
23 the experience of the plan and to reasonable expecta-
24 tions; and

1 “(2) represent such actuary’s best estimate of
2 anticipated experience under the plan.

3 The opinion by the qualified actuary shall be made with
4 respect to, and shall be made a part of, the annual report.

5 **“SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TER-**
6 **MINATION.**

7 “Except as provided in section 809(b), an association
8 health plan which is or has been certified under this part
9 may terminate (upon or at any time after cessation of ac-
10 cruals in benefit liabilities) only if the board of trustees—

11 “(1) not less than 60 days before the proposed
12 termination date, provides to the participants and
13 beneficiaries a written notice of intent to terminate
14 stating that such termination is intended and the
15 proposed termination date;

16 “(2) develops a plan for winding up the affairs
17 of the plan in connection with such termination in
18 a manner which will result in timely payment of all
19 benefits for which the plan is obligated; and

20 “(3) submits such plan in writing to the appli-
21 cable authority.

22 Actions required under this section shall be taken in such
23 form and manner as may be prescribed by the applicable
24 authority by regulation through negotiated rulemaking.

1 **“SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMI-**
2 **NATION.**

3 “(a) ACTIONS TO AVOID DEPLETION OF RE-
4 SERVES.—An association health plan which is certified
5 under this part and which provides benefits other than
6 health insurance coverage shall continue to meet the re-
7 quirements of section 806, irrespective of whether such
8 certification continues in effect. The board of trustees of
9 such plan shall determine quarterly whether the require-
10 ments of section 806 are met. In any case in which the
11 board determines that there is reason to believe that there
12 is or will be a failure to meet such requirements, or the
13 applicable authority makes such a determination and so
14 notifies the board, the board shall immediately notify the
15 qualified actuary engaged by the plan, and such actuary
16 shall, not later than the end of the next following month,
17 make such recommendations to the board for corrective
18 action as the actuary determines necessary to ensure com-
19 pliance with section 806. Not later than 30 days after re-
20 ceiving from the actuary recommendations for corrective
21 actions, the board shall notify the applicable authority (in
22 such form and manner as the applicable authority may
23 prescribe by regulation through negotiated rulemaking) of
24 such recommendations of the actuary for corrective action,
25 together with a description of the actions (if any) that the
26 board has taken or plans to take in response to such rec-

ommendations. The board shall thereafter report to the applicable authority, in such form and frequency as the applicable authority may specify to the board, regarding corrective action taken by the board until the requirements of section 806 are met.

“(b) MANDATORY TERMINATION.—In any case in which—

“(1) the applicable authority has been notified under subsection (a) of a failure of an association health plan which is or has been certified under this part and is described in section 806(a)(2) to meet the requirements of section 806 and has not been notified by the board of trustees of the plan that corrective action has restored compliance with such requirements; and

“(2) the applicable authority determines that there is a reasonable expectation that the plan will continue to fail to meet the requirements of section 806,

the board of trustees of the plan shall, at the direction of the applicable authority, terminate the plan and, in the course of the termination, take such actions as the applicable authority may require, including satisfying any claims referred to in section 806(a)(2)(B)(iii) and recovering for the plan any liability under subsection

1 (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure
2 that the affairs of the plan will be, to the maximum extent
3 possible, wound up in a manner which will result in timely
4 provision of all benefits for which the plan is obligated.

5 **“SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOL-**
6 **VENT ASSOCIATION HEALTH PLANS PRO-**
7 **VIDING HEALTH BENEFITS IN ADDITION TO**
8 **HEALTH INSURANCE COVERAGE.**

9 “(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR
10 INSOLVENT PLANS.—Whenever the Secretary determines
11 that an association health plan which is or has been cer-
12 tified under this part and which is described in section
13 806(a)(2) will be unable to provide benefits when due or
14 is otherwise in a financially hazardous condition, as shall
15 be defined by the Secretary by regulation through nego-
16 tiated rulemaking, the Secretary shall, upon notice to the
17 plan, apply to the appropriate United States district court
18 for appointment of the Secretary as trustee to administer
19 the plan for the duration of the insolvency. The plan may
20 appear as a party and other interested persons may inter-
21 vene in the proceedings at the discretion of the court. The
22 court shall appoint such Secretary trustee if the court de-
23 termines that the trusteeship is necessary to protect the
24 interests of the participants and beneficiaries or providers
25 of medical care or to avoid any unreasonable deterioration

1 of the financial condition of the plan. The trusteeship of
2 such Secretary shall continue until the conditions de-
3 scribed in the first sentence of this subsection are rem-
4 edied or the plan is terminated.

5 “(b) POWERS AS TRUSTEE.—The Secretary, upon
6 appointment as trustee under subsection (a), shall have
7 the power—

8 “(1) to do any act authorized by the plan, this
9 title, or other applicable provisions of law to be done
10 by the plan administrator or any trustee of the plan;

11 “(2) to require the transfer of all (or any part)
12 of the assets and records of the plan to the Sec-
13 retary as trustee;

14 “(3) to invest any assets of the plan which the
15 Secretary holds in accordance with the provisions of
16 the plan, regulations prescribed by the Secretary
17 through negotiated rulemaking, and applicable provi-
18 sions of law;

19 “(4) to require the sponsor, the plan adminis-
20 trator, any participating employer, and any employee
21 organization representing plan participants to fur-
22 nish any information with respect to the plan which
23 the Secretary as trustee may reasonably need in
24 order to administer the plan;

1 “(5) to collect for the plan any amounts due the
2 plan and to recover reasonable expenses of the trust-
3 eeship;

4 “(6) to commence, prosecute, or defend on be-
5 half of the plan any suit or proceeding involving the
6 plan;

7 “(7) to issue, publish, or file such notices, state-
8 ments, and reports as may be required by the Sec-
9 retary by regulation through negotiated rulemaking
10 or required by any order of the court;

11 “(8) to terminate the plan (or provide for its
12 termination accordance with section 809(b)) and liq-
13 uidate the plan assets, to restore the plan to the re-
14 sponsibility of the sponsor, or to continue the trust-
15 eeship;

16 “(9) to provide for the enrollment of plan par-
17 ticipants and beneficiaries under appropriate cov-
18 erage options; and

19 “(10) to do such other acts as may be nec-
20 essary to comply with this title or any order of the
21 court and to protect the interests of plan partici-
22 pants and beneficiaries and providers of medical
23 care.

1 “(c) NOTICE OF APPOINTMENT.—As soon as prac-
2 ticable after the Secretary’s appointment as trustee, the
3 Secretary shall give notice of such appointment to—

4 “(1) the sponsor and plan administrator;

5 “(2) each participant;

6 “(3) each participating employer; and

7 “(4) if applicable, each employee organization
8 which, for purposes of collective bargaining, rep-
9 resents plan participants.

10 “(d) ADDITIONAL DUTIES.—Except to the extent in-
11 consistent with the provisions of this title, or as may be
12 otherwise ordered by the court, the Secretary, upon ap-
13 pointment as trustee under this section, shall be subject
14 to the same duties as those of a trustee under section 704
15 of title 11, United States Code, and shall have the duties
16 of a fiduciary for purposes of this title.

17 “(e) OTHER PROCEEDINGS.—An application by the
18 Secretary under this subsection may be filed notwith-
19 standing the pendency in the same or any other court of
20 any bankruptcy, mortgage foreclosure, or equity receiver-
21 ship proceeding, or any proceeding to reorganize, conserve,
22 or liquidate such plan or its property, or any proceeding
23 to enforce a lien against property of the plan.

24 “(f) JURISDICTION OF COURT.—

1 “(1) IN GENERAL.—Upon the filing of an appli-
2 cation for the appointment as trustee or the issuance
3 of a decree under this section, the court to which the
4 application is made shall have exclusive jurisdiction
5 of the plan involved and its property wherever lo-
6 cated with the powers, to the extent consistent with
7 the purposes of this section, of a court of the United
8 States having jurisdiction over cases under chapter
9 11 of title 11, United States Code. Pending an adju-
10 dication under this section such court shall stay, and
11 upon appointment by it of the Secretary as trustee,
12 such court shall continue the stay of, any pending
13 mortgage foreclosure, equity receivership, or other
14 proceeding to reorganize, conserve, or liquidate the
15 plan, the sponsor, or property of such plan or spon-
16 sor, and any other suit against any receiver, conser-
17 vator, or trustee of the plan, the sponsor, or prop-
18 erty of the plan or sponsor. Pending such adjudica-
19 tion and upon the appointment by it of the Sec-
20 retary as trustee, the court may stay any proceeding
21 to enforce a lien against property of the plan or the
22 sponsor or any other suit against the plan or the
23 sponsor.

24 “(2) VENUE.—An action under this section
25 may be brought in the judicial district where the

1 sponsor or the plan administrator resides or does
2 business or where any asset of the plan is situated.

3 A district court in which such action is brought may
4 issue process with respect to such action in any
5 other judicial district.

6 “(g) PERSONNEL.—In accordance with regulations
7 which shall be prescribed by the Secretary through nego-
8 tiated rulemaking, the Secretary shall appoint, retain, and
9 compensate accountants, actuaries, and other professional
10 service personnel as may be necessary in connection with
11 the Secretary’s service as trustee under this section.

12 **“SEC. 811. STATE ASSESSMENT AUTHORITY.**

13 “(a) IN GENERAL.—Notwithstanding section 514, a
14 State may impose by law a contribution tax on an associa-
15 tion health plan described in section 806(a)(2), if the plan
16 commenced operations in such State after the date of the
17 enactment of the Comprehensive Access and Responsi-
18 bility in Health Care Act of 1999.

19 “(b) CONTRIBUTION TAX.—For purposes of this sec-
20 tion, the term ‘contribution tax’ imposed by a State on
21 an association health plan means any tax imposed by such
22 State if—

23 “(1) such tax is computed by applying a rate to
24 the amount of premiums or contributions, with re-
25 spect to individuals covered under the plan who are

1 residents of such State, which are received by the
2 plan from participating employers located in such
3 State or from such individuals;

4 “(2) the rate of such tax does not exceed the
5 rate of any tax imposed by such State on premiums
6 or contributions received by insurers or health main-
7 tenance organizations for health insurance coverage
8 offered in such State in connection with a group
9 health plan;

10 “(3) such tax is otherwise nondiscriminatory;
11 and

12 “(4) the amount of any such tax assessed on
13 the plan is reduced by the amount of any tax or as-
14 sessment otherwise imposed by the State on pre-
15 miums, contributions, or both received by insurers or
16 health maintenance organizations for health insur-
17 ance coverage, aggregate excess/stop loss insurance
18 (as defined in section 806(g)(1)), specific excess/
19 stop loss insurance (as defined in section 806(g)(2)),
20 other insurance related to the provision of medical
21 care under the plan, or any combination thereof pro-
22 vided by such insurers or health maintenance organi-
23 zations in such State in connection with such plan.

24 **“SEC. 812. DEFINITIONS AND RULES OF CONSTRUCTION.**

25 “(a) DEFINITIONS.—For purposes of this part—

1 “(1) GROUP HEALTH PLAN.—The term ‘group
2 health plan’ has the meaning provided in section
3 733(a)(1) (after applying subsection (b) of this sec-
4 tion).

5 “(2) MEDICAL CARE.—The term ‘medical care’
6 has the meaning provided in section 733(a)(2).

7 “(3) HEALTH INSURANCE COVERAGE.—The
8 term ‘health insurance coverage’ has the meaning
9 provided in section 733(b)(1).

10 “(4) HEALTH INSURANCE ISSUER.—The term
11 ‘health insurance issuer’ has the meaning provided
12 in section 733(b)(2).

13 “(5) APPLICABLE AUTHORITY.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (B), the term ‘applicable author-
16 ity’ means, in connection with an association
17 health plan—

18 “(i) the State recognized pursuant to
19 subsection (c) of section 506 as the State
20 to which authority has been delegated in
21 connection with such plan; or

22 “(ii) if there if no State referred to in
23 clause (i), the Secretary.

24 “(B) EXCEPTIONS.—

1 “(i) JOINT AUTHORITIES.—Where
2 such term appears in section 808(3), sec-
3 tion 807(e) (in the first instance), section
4 809(a) (in the second instance), section
5 809(a) (in the fourth instance), and sec-
6 tion 809(b)(1), such term means, in con-
7 nection with an association health plan, the
8 Secretary and the State referred to in sub-
9 paragraph (A)(i) (if any) in connection
10 with such plan.

11 “(ii) REGULATORY AUTHORITIES.—
12 Where such term appears in section 802(a)
13 (in the first instance), section 802(d), sec-
14 tion 802(e), section 803(d), section
15 805(a)(5), section 806(a)(2), section
16 806(b), section 806(c), section 806(d),
17 paragraphs (1)(A) and (2)(A) of section
18 806(g), section 806(h), section 806(i), sec-
19 tion 806(j), section 807(a) (in the second
20 instance), section 807(b), section 807(d),
21 section 807(e) (in the second instance),
22 section 808 (in the matter after paragraph
23 (3)), and section 809(a) (in the third in-
24 stance), such term means, in connection

1 with an association health plan, the Sec-
2 retary.

3 “(6) HEALTH STATUS-RELATED FACTOR.—The
4 term ‘health status-related factor’ has the meaning
5 provided in section 733(d)(2).

6 “(7) INDIVIDUAL MARKET.—

7 “(A) IN GENERAL.—The term ‘individual
8 market’ means the market for health insurance
9 coverage offered to individuals other than in
10 connection with a group health plan.

11 “(B) TREATMENT OF VERY SMALL
12 GROUPS.—

13 “(i) IN GENERAL.—Subject to clause
14 (ii), such term includes coverage offered in
15 connection with a group health plan that
16 has fewer than 2 participants as current
17 employees or participants described in sec-
18 tion 732(d)(3) on the first day of the plan
19 year.

20 “(ii) STATE EXCEPTION.—Clause (i)
21 shall not apply in the case of health insur-
22 ance coverage offered in a State if such
23 State regulates the coverage described in
24 such clause in the same manner and to the
25 same extent as coverage in the small group

1 market (as defined in section 2791(e)(5) of
2 the Public Health Service Act) is regulated
3 by such State.

4 “(8) PARTICIPATING EMPLOYER.—The term
5 ‘participating employer’ means, in connection with
6 an association health plan, any employer, if any indi-
7 vidual who is an employee of such employer, a part-
8 ner in such employer, or a self-employed individual
9 who is such employer (or any dependent, as defined
10 under the terms of the plan, of such individual) is
11 or was covered under such plan in connection with
12 the status of such individual as such an employee,
13 partner, or self-employed individual in relation to the
14 plan.

15 “(9) APPLICABLE STATE AUTHORITY.—The
16 term ‘applicable State authority’ means, with respect
17 to a health insurance issuer in a State, the State in-
18 surance commissioner or official or officials des-
19 ignated by the State to enforce the requirements of
20 title XXVII of the Public Health Service Act for the
21 State involved with respect to such issuer.

22 “(10) QUALIFIED ACTUARY.—The term ‘quali-
23 fied actuary’ means an individual who is a member
24 of the American Academy of Actuaries or meets
25 such reasonable standards and qualifications as the

1 Secretary may provide by regulation through nego-
2 tiated rulemaking.

3 “(11) AFFILIATED MEMBER.—The term ‘affili-
4 ated member’ means, in connection with a sponsor—

5 “(A) a person who is otherwise eligible to
6 be a member of the sponsor but who elects an
7 affiliated status with the sponsor,

8 “(B) in the case of a sponsor with mem-
9 bers which consist of associations, a person who
10 is a member of any such association and elects
11 an affiliated status with the sponsor, or

12 “(C) in the case of an association health
13 plan in existence on the date of the enactment
14 of the Comprehensive Access and Responsibility
15 in Health Care Act of 1999, a person eligible
16 to be a member of the sponsor or one of its
17 member associations.

18 “(12) LARGE EMPLOYER.—The term ‘large em-
19 ployer’ means, in connection with a group health
20 plan with respect to a plan year, an employer who
21 employed an average of at least 51 employees on
22 business days during the preceding calendar year
23 and who employs at least 2 employees on the first
24 day of the plan year.

1 “(13) SMALL EMPLOYER.—The term ‘small em-
2 ployer’ means, in connection with a group health
3 plan with respect to a plan year, an employer who
4 is not a large employer.

5 “(b) RULES OF CONSTRUCTION.—

6 “(1) EMPLOYERS AND EMPLOYEES.—For pur-
7 poses of determining whether a plan, fund, or pro-
8 gram is an employee welfare benefit plan which is an
9 association health plan, and for purposes of applying
10 this title in connection with such plan, fund, or pro-
11 gram so determined to be such an employee welfare
12 benefit plan—

13 “(A) in the case of a partnership, the term
14 ‘employer’ (as defined in section (3)(5)) in-
15 cludes the partnership in relation to the part-
16 ners, and the term ‘employee’ (as defined in
17 section (3)(6)) includes any partner in relation
18 to the partnership; and

19 “(B) in the case of a self-employed indi-
20 vidual, the term ‘employer’ (as defined in sec-
21 tion 3(5)) and the term ‘employee’ (as defined
22 in section 3(6)) shall include such individual.

23 “(2) PLANS, FUNDS, AND PROGRAMS TREATED
24 AS EMPLOYEE WELFARE BENEFIT PLANS.—In the
25 case of any plan, fund, or program which was estab-

lished or is maintained for the purpose of providing medical care (through the purchase of insurance or otherwise) for employees (or their dependents) covered thereunder and which demonstrates to the Secretary that all requirements for certification under this part would be met with respect to such plan, fund, or program if such plan, fund, or program were a group health plan, such plan, fund, or program shall be treated for purposes of this title as an employee welfare benefit plan on and after the date of such demonstration.

“(c) APPLICABILITY ONLY WITH RESPECT TO INCLUDED GROUP HEALTH PLAN BENEFITS.—

“(1) IN GENERAL.—The requirements for certification under this part in the case of any association health plan shall apply only in connection with included group health plan benefits provided under such plan.

“(2) INCLUDED GROUP HEALTH PLAN BENEFITS.—For purposes of paragraph (1), the term ‘included group health plan benefit’ means a benefit which is not an excepted benefit (as defined in section 733(e)).”.

(b) CONFORMING AMENDMENTS TO PREEMPTION RULES.—

1 (1) Section 514(b)(6) of such Act (29 U.S.C.
2 1144(b)(6)) is amended by adding at the end the
3 following new subparagraph:

4 “(E) The preceding subparagraphs of this paragraph
5 do not apply with respect to any State law in the case
6 of an association health plan which is certified under part
7 8.”.

8 (2) Section 514 of such Act (29 U.S.C. 1144)
9 is amended—

10 (A) in subsection (b)(4), by striking “Sub-
11 section (a)” and inserting “Subsections (a) and
12 (d)”;

13 (B) in subsection (b)(5), by striking “sub-
14 section (a)” in subparagraph (A) and inserting
15 “subsection (a) of this section and subsections
16 (a)(2)(B) and (b) of section 805”, and by strik-
17 ing “subsection (a)” in subparagraph (B) and
18 inserting “subsection (a) of this section or sub-
19 section (a)(2)(B) or (b) of section 805”;

20 (C) by redesignating subsection (d) as sub-
21 section (e); and

22 (D) by inserting after subsection (c) the
23 following new subsection:

24 “(d)(1) Except as provided in subsection (b)(4), the
25 provisions of this title shall supersede any and all State

1 laws insofar as they may now or hereafter preclude, or
2 have the effect of precluding, a health insurance issuer
3 from offering health insurance coverage in connection with
4 an association health plan which is certified under part
5 8.

6 “(2) Except as provided in paragraphs (4) and (5)
7 of subsection (b) of this section—

8 “(A) In any case in which health insurance cov-
9 erage of any policy type is offered under an associa-
10 tion health plan certified under part 8 to a partici-
11 pating employer operating in such State, the provi-
12 sions of this title shall supersede any and all laws
13 of such State insofar as they may preclude a health
14 insurance issuer from offering health insurance cov-
15 erage of the same policy type to other employers op-
16 erating in the State which are eligible for coverage
17 under such association health plan, whether or not
18 such other employers are participating employers in
19 such plan.

20 “(B) In any case in which health insurance cov-
21 erage of any policy type is offered under an associa-
22 tion health plan in a State and the filing, with the
23 applicable State authority, of the policy form in con-
24 nection with such policy type is approved by such
25 State authority, the provisions of this title shall su-

1 persede any and all laws of any other State in which
2 health insurance coverage of such type is offered, in-
3 sofar as they may preclude, upon the filing in the
4 same form and manner of such policy form with the
5 applicable State authority in such other State, the
6 approval of the filing in such other State.

7 “(3) For additional provisions relating to association
8 health plans, see subsections (a)(2)(B) and (b) of section
9 805.

10 “(4) For purposes of this subsection, the term ‘asso-
11 ciation health plan’ has the meaning provided in section
12 801(a), and the terms ‘health insurance coverage’, ‘par-
13 ticipating employer’, and ‘health insurance issuer’ have
14 the meanings provided such terms in section 811, respec-
15 tively.”.

16 (3) Section 514(b)(6)(A) of such Act (29
17 U.S.C. 1144(b)(6)(A)) is amended—

18 (A) in clause (i)(II), by striking “and” at
19 the end;

20 (B) in clause (ii), by inserting “and which
21 does not provide medical care (within the mean-
22 ing of section 733(a)(2)),” after “arrange-
23 ment,” and by striking “title.” and inserting
24 “title, and”; and

(C) by adding at the end the following new clause:

“(iii) subject to subparagraph (E), in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement and which provides medical care (within the meaning of section 733(a)(2)), any law of any State which regulates insurance may apply.”.

(4) Section 514(e) of such Act (as redesignated by paragraph (2)(C)) is amended—

(A) by striking “Nothing” and inserting “(1) Except as provided in paragraph (2), nothing”; and

(B) by adding at the end the following new paragraph:

“(2) Nothing in any other provision of law enacted on or after the date of the enactment of the Comprehensive Access and Responsibility in Health Care Act of 1999 shall be construed to alter, amend, modify, invalidate, impair, or supersede any provision of this title, except by specific cross-reference to the affected section.”.

(c) PLAN SPONSOR.—Section 3(16)(B) of such Act (29 U.S.C. 102(16)(B)) is amended by adding at the end the following new sentence: “Such term also includes a

1 person serving as the sponsor of an association health plan
2 under part 8.”.

3 (d) DISCLOSURE OF SOLVENCY PROTECTIONS RE-
4 LATED TO SELF-INSURED AND FULLY INSURED OPTIONS
5 UNDER ASSOCIATION HEALTH PLANS.—Section 102(b)
6 of such Act (29 U.S.C. 102(b)) is amended by adding at
7 the end the following: “An association health plan shall
8 include in its summary plan description, in connection
9 with each benefit option, a description of the form of sol-
10 vency or guarantee fund protection secured pursuant to
11 this Act or applicable State law, if any.”.

12 (e) SAVINGS CLAUSE.—Section 731(c) of such Act is
13 amended by inserting “or part 8” after “this part”.

14 (f) REPORT TO THE CONGRESS REGARDING CERTIFI-
15 CATION OF SELF-INSURED ASSOCIATION HEALTH
16 PLANS.—Not later than January 1, 2004, the Secretary
17 of Labor shall report to the Committee on Education and
18 the Workforce of the House of Representatives and the
19 Committee on Health, Education, Labor, and Pensions of
20 the Senate the effect association health plans have had,
21 if any, on reducing the number of uninsured individuals.

22 (g) CLERICAL AMENDMENT.—The table of contents
23 in section 1 of the Employee Retirement Income Security
24 Act of 1974 is amended by inserting after the item relat-
25 ing to section 734 the following new items:

“PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

- “Sec. 801. Association health plans.
- “Sec. 802. Certification of association health plans.
- “Sec. 803. Requirements relating to sponsors and boards of trustees.
- “Sec. 804. Participation and coverage requirements.
- “Sec. 805. Other requirements relating to plan documents, contribution rates, and benefit options.
- “Sec. 806. Maintenance of reserves and provisions for solvency for plans providing health benefits in addition to health insurance coverage.
- “Sec. 807. Requirements for application and related requirements.
- “Sec. 808. Notice requirements for voluntary termination.
- “Sec. 809. Corrective actions and mandatory termination.
- “Sec. 810. Trusteeship by the Secretary of insolvent association health plans providing health benefits in addition to health insurance coverage.
- “Sec. 811. State assessment authority.
- “Sec. 812. Definitions and rules of construction.”.

1 SEC. 132. CLARIFICATION OF TREATMENT OF SINGLE EM-
2 PLOYER ARRANGEMENTS.

3 Section 3(40)(B) of the Employee Retirement Income
4 Security Act of 1974 (29 U.S.C. 1002(40)(B)) is
5 amended—

6 (1) in clause (i), by inserting “for any plan year
7 of any such plan, or any fiscal year of any such
8 other arrangement;” after “single employer”, and by
9 inserting “during such year or at any time during
10 the preceding 1-year period” after “control group”;

11 (2) in clause (iii)—

12 (A) by striking “common control shall not
13 be based on an interest of less than 25 percent”
14 and inserting “an interest of greater than 25
15 percent may not be required as the minimum
16 interest necessary for common control”; and

1 (B) by striking “similar to” and inserting
2 “consistent and coextensive with”;

3 (3) by redesignating clauses (iv) and (v) as
4 clauses (v) and (vi), respectively; and

5 (4) by inserting after clause (iii) the following
6 new clause:

7 “(iv) in determining, after the application of
8 clause (i), whether benefits are provided to employ-
9 ees of two or more employers, the arrangement shall
10 be treated as having only one participating employer
11 if, after the application of clause (i), the number of
12 individuals who are employees and former employees
13 of any one participating employer and who are cov-
14 ered under the arrangement is greater than 75 per-
15 cent of the aggregate number of all individuals who
16 are employees or former employees of participating
17 employers and who are covered under the arrange-
18 ment;”.

19 **SEC. 133. CLARIFICATION OF TREATMENT OF CERTAIN**
20 **COLLECTIVELY BARGAINED ARRANGE-**
21 **MENTS.**

22 (a) IN GENERAL.—Section 3(40)(A)(i) of the Em-
23 ployee Retirement Income Security Act of 1974 (29
24 U.S.C. 1002(40)(A)(i)) is amended to read as follows:

1 “(i)(I) under or pursuant to one or more collec-
2 tive bargaining agreements which are reached pursu-
3 ant to collective bargaining described in section 8(d)
4 of the National Labor Relations Act (29 U.S.C.
5 158(d)) or paragraph Fourth of section 2 of the
6 Railway Labor Act (45 U.S.C. 152, paragraph
7 Fourth) or which are reached pursuant to labor-
8 management negotiations under similar provisions of
9 State public employee relations laws, and (II) in ac-
10 cordance with subparagraphs (C), (D), and (E);”.

11 (b) LIMITATIONS.—Section 3(40) of such Act (29
12 U.S.C. 1002(40)) is amended by adding at the end the
13 following new subparagraphs:

14 “(C) For purposes of subparagraph (A)(i)(II), a plan
15 or other arrangement shall be treated as established or
16 maintained in accordance with this subparagraph only if
17 the following requirements are met:

18 “(i) The plan or other arrangement, and the
19 employee organization or any other entity sponsoring
20 the plan or other arrangement, do not—

21 “(I) utilize the services of any licensed in-
22 surance agent or broker for soliciting or enroll-
23 ing employers or individuals as participating
24 employers or covered individuals under the plan
25 or other arrangement; or

1 “(II) pay any type of compensation to a
2 person, other than a full time employee of the
3 employee organization (or a member of the or-
4 ganization to the extent provided in regulations
5 prescribed by the Secretary through negotiated
6 rulemaking), that is related either to the volume
7 or number of employers or individuals solicited
8 or enrolled as participating employers or cov-
9 ered individuals under the plan or other ar-
10 rangement, or to the dollar amount or size of
11 the contributions made by participating employ-
12 ers or covered individuals to the plan or other
13 arrangement;

14 except to the extent that the services used by the
15 plan, arrangement, organization, or other entity con-
16 sist solely of preparation of documents necessary for
17 compliance with the reporting and disclosure re-
18 quirements of part 1 or administrative, investment,
19 or consulting services unrelated to solicitation or en-
20 rollment of covered individuals.

21 “(ii) As of the end of the preceding plan year,
22 the number of covered individuals under the plan or
23 other arrangement who are neither—

24 “(I) employed within a bargaining unit
25 covered by any of the collective bargaining

1 agreements with a participating employer (nor
2 covered on the basis of an individual's employ-
3 ment in such a bargaining unit); nor

4 “(II) present employees (or former employ-
5 ees who were covered while employed) of the
6 sponsoring employee organization, of an em-
7 ployer who is or was a party to any of the col-
8 lective bargaining agreements, or of the plan or
9 other arrangement or a related plan or arrange-
10 ment (nor covered on the basis of such present
11 or former employment);

12 does not exceed 15 percent of the total number of
13 individuals who are covered under the plan or ar-
14 rangement and who are present or former employees
15 who are or were covered under the plan or arrange-
16 ment pursuant to a collective bargaining agreement
17 with a participating employer. The requirements of
18 the preceding provisions of this clause shall be treat-
19 ed as satisfied if, as of the end of the preceding plan
20 year, such covered individuals are comprised solely
21 of individuals who were covered individuals under
22 the plan or other arrangement as of the date of the
23 enactment of the Comprehensive Access and Respon-
24 sibility in Health Care Act of 1999 and, as of the
25 end of the preceding plan year, the number of such

1 covered individuals does not exceed 25 percent of the
2 total number of present and former employees en-
3 rolled under the plan or other arrangement.

4 “(iii) The employee organization or other entity
5 sponsoring the plan or other arrangement certifies
6 to the Secretary each year, in a form and manner
7 which shall be prescribed by the Secretary through
8 negotiated rulemaking that the plan or other ar-
9 rangement meets the requirements of clauses (i) and
10 (ii).

11 “(D) For purposes of subparagraph (A)(i)(II), a plan
12 or arrangement shall be treated as established or main-
13 tained in accordance with this subparagraph only if—

14 “(i) all of the benefits provided under the plan
15 or arrangement consist of health insurance coverage;
16 or

17 “(ii)(I) the plan or arrangement is a multiem-
18 ployer plan; and

19 “(II) the requirements of clause (B) of the pro-
20 viso to clause (5) of section 302(c) of the Labor
21 Management Relations Act, 1947 (29 U.S.C.
22 186(c)) are met with respect to such plan or other
23 arrangement.

1 “(E) For purposes of subparagraph (A)(i)(II), a plan
 2 or arrangement shall be treated as established or main-
 3 tained in accordance with this subparagraph only if—

4 “(i) the plan or arrangement is in effect as of
 5 the date of the enactment of the Comprehensive Ac-
 6 cess and Responsibility in Health Care Act of 1999;
 7 or

8 “(ii) the employee organization or other entity
 9 sponsoring the plan or arrangement—

10 “(I) has been in existence for at least 3
 11 years; or

12 “(II) demonstrates to the satisfaction of
 13 the Secretary that the requirements of subpara-
 14 graphs (C) and (D) are met with respect to the
 15 plan or other arrangement.”.

16 (c) CONFORMING AMENDMENTS TO DEFINITIONS OF
 17 PARTICIPANT AND BENEFICIARY.—Section 3(7) of such
 18 Act (29 U.S.C. 1002(7)) is amended by adding at the end
 19 the following new sentence: “Such term includes an indi-
 20 vidual who is a covered individual described in paragraph
 21 (40)(C)(ii).”.

22 **SEC. 134. ENFORCEMENT PROVISIONS RELATING TO ASSO-**
 23 **CIATION HEALTH PLANS.**

24 (a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL
 25 MISREPRESENTATIONS.—Section 501 of the Employee

1 Retirement Income Security Act of 1974 (29 U.S.C. 1131)
2 is amended—

3 (1) by inserting “(a)” after “SEC. 501.”; and

4 (2) by adding at the end the following new sub-
5 section:

6 “(b) Any person who willfully falsely represents, to
7 any employee, any employee’s beneficiary, any employer,
8 the Secretary, or any State, a plan or other arrangement
9 established or maintained for the purpose of offering or
10 providing any benefit described in section 3(1) to employ-
11 ees or their beneficiaries as—

12 “(1) being an association health plan which has
13 been certified under part 8;

14 “(2) having been established or maintained
15 under or pursuant to one or more collective bar-
16 gaining agreements which are reached pursuant to
17 collective bargaining described in section 8(d) of the
18 National Labor Relations Act (29 U.S.C. 158(d)) or
19 paragraph Fourth of section 2 of the Railway Labor
20 Act (45 U.S.C. 152, paragraph Fourth) or which are
21 reached pursuant to labor-management negotiations
22 under similar provisions of State public employee re-
23 lations laws; or

1 “(3) being a plan or arrangement with respect
2 to which the requirements of subparagraph (C), (D),
3 or (E) of section 3(40) are met;
4 shall, upon conviction, be imprisoned not more than 5
5 years, be fined under title 18, United States Code, or
6 both.”.

7 (b) CEASE ACTIVITIES ORDERS.—Section 502 of
8 such Act (29 U.S.C. 1132) is amended by adding at the
9 end the following new subsection:

10 “(n)(1) Subject to paragraph (2), upon application
11 by the Secretary showing the operation, promotion, or
12 marketing of an association health plan (or similar ar-
13 rangement providing benefits consisting of medical care
14 (as defined in section 733(a)(2))) that—

15 “(A) is not certified under part 8, is subject
16 under section 514(b)(6) to the insurance laws of any
17 State in which the plan or arrangement offers or
18 provides benefits, and is not licensed, registered, or
19 otherwise approved under the insurance laws of such
20 State; or

21 “(B) is an association health plan certified
22 under part 8 and is not operating in accordance with
23 the requirements under part 8 for such certification,
24 a district court of the United States shall enter an order
25 requiring that the plan or arrangement cease activities.

1 “(2) Paragraph (1) shall not apply in the case of an
2 association health plan or other arrangement if the plan
3 or arrangement shows that—

4 “(A) all benefits under it referred to in para-
5 graph (1) consist of health insurance coverage; and

6 “(B) with respect to each State in which the
7 plan or arrangement offers or provides benefits, the
8 plan or arrangement is operating in accordance with
9 applicable State laws that are not superseded under
10 section 514.

11 “(3) The court may grant such additional equitable
12 relief, including any relief available under this title, as it
13 deems necessary to protect the interests of the public and
14 of persons having claims for benefits against the plan.”.

15 (c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—
16 Section 503 of such Act (29 U.S.C. 1133) (as amended
17 by title I) is amended by adding at the end the following
18 new subsection:

19 “(c) ASSOCIATION HEALTH PLANS.—The terms of
20 each association health plan which is or has been certified
21 under part 8 shall require the board of trustees or the
22 named fiduciary (as applicable) to ensure that the require-
23 ments of this section are met in connection with claims
24 filed under the plan.”.

1 **SEC. 135. COOPERATION BETWEEN FEDERAL AND STATE**
2 **AUTHORITIES.**

3 Section 506 of the Employee Retirement Income Se-
4 curity Act of 1974 (29 U.S.C. 1136) is amended by adding
5 at the end the following new subsection:

6 “(c) **RESPONSIBILITY OF STATES WITH RESPECT TO**
7 **ASSOCIATION HEALTH PLANS.**—

8 “(1) **AGREEMENTS WITH STATES.**—A State
9 may enter into an agreement with the Secretary for
10 delegation to the State of some or all of—

11 “(A) the Secretary’s authority under sec-
12 tions 502 and 504 to enforce the requirements
13 for certification under part 8;

14 “(B) the Secretary’s authority to certify
15 association health plans under part 8 in accord-
16 ance with regulations of the Secretary applica-
17 ble to certification under part 8; or

18 “(C) any combination of the Secretary’s
19 authority authorized to be delegated under sub-
20 paragraphs (A) and (B).

21 “(2) **DELEGATIONS.**—Any department, agency,
22 or instrumentality of a State to which authority is
23 delegated pursuant to an agreement entered into
24 under this paragraph may, if authorized under State
25 law and to the extent consistent with such agree-

1 ment, exercise the powers of the Secretary under
2 this title which relate to such authority.

3 “(3) RECOGNITION OF PRIMARY DOMICILE
4 STATE.—In entering into any agreement with a
5 State under subparagraph (A), the Secretary shall
6 ensure that, as a result of such agreement and all
7 other agreements entered into under subparagraph
8 (A), only one State will be recognized, with respect
9 to any particular association health plan, as the
10 State to which all authority has been delegated pur-
11 suant to such agreements in connection with such
12 plan. In carrying out this paragraph, the Secretary
13 shall take into account the places of residence of the
14 participants and beneficiaries under the plan and the
15 State in which the trust is maintained.”.

16 **SEC. 136. EFFECTIVE DATE AND TRANSITIONAL AND**
17 **OTHER RULES.**

18 (a) EFFECTIVE DATE.—The amendments made by
19 sections 131, 134, and 135 shall take effect on January
20 1, 2001. The amendments made by sections 132 and 133
21 shall take effect on the date of the enactment of this Act.
22 The Secretary of Labor shall first issue all regulations
23 necessary to carry out the amendments made by this sub-
24 title before January 1, 2001. Such regulations shall be
25 issued through negotiated rulemaking.

1 (b) EXCEPTION.—Section 801(a)(2) of the Employee
2 Retirement Income Security Act of 1974 (added by section
3 131) does not apply in connection with an association
4 health plan (certified under part 8 of subtitle B of title
5 I of such Act) existing on the date of the enactment of
6 this Act, if no benefits provided thereunder as of the date
7 of the enactment of this Act consist of health insurance
8 coverage (as defined in section 733(b)(1) of such Act).

9 (c) TREATMENT OF CERTAIN EXISTING HEALTH
10 BENEFITS PROGRAMS.—

11 (1) IN GENERAL.—In any case in which, as of
12 the date of the enactment of this Act, an arrange-
13 ment is maintained in a State for the purpose of
14 providing benefits consisting of medical care for the
15 employees and beneficiaries of its participating em-
16 ployers, at least 200 participating employers make
17 contributions to such arrangement, such arrange-
18 ment has been in existence for at least 10 years, and
19 such arrangement is licensed under the laws of one
20 or more States to provide such benefits to its par-
21 ticipating employers, upon the filing with the appli-
22 cable authority (as defined in section 812(a)(5) of
23 the Employee Retirement Income Security Act of
24 1974 (as amended by this subtitle)) by the arrange-
25 ment of an application for certification of the ar-

1 rangement under part 8 of subtitle B of title I of
2 such Act—

3 (A) such arrangement shall be deemed to
4 be a group health plan for purposes of title I
5 of such Act;

6 (B) the requirements of sections 801(a)(1)
7 and 803(a)(1) of the Employee Retirement In-
8 come Security Act of 1974 shall be deemed met
9 with respect to such arrangement;

10 (C) the requirements of section 803(b) of
11 such Act shall be deemed met, if the arrange-
12 ment is operated by a board of directors
13 which—

14 (i) is elected by the participating em-
15 ployers, with each employer having one
16 vote; and

17 (ii) has complete fiscal control over
18 the arrangement and which is responsible
19 for all operations of the arrangement;

20 (D) the requirements of section 804(a) of
21 such Act shall be deemed met with respect to
22 such arrangement; and

23 (E) the arrangement may be certified by
24 any applicable authority with respect to its op-

erations in any State only if it operates in such State on the date of certification.

The provisions of this subsection shall cease to apply with respect to any such arrangement at such time after the date of the enactment of this Act as the applicable requirements of this subsection are not met with respect to such arrangement.

(2) DEFINITIONS.—For purposes of this subsection, the terms “group health plan”, “medical care”, and “participating employer” shall have the meanings provided in section 812 of the Employee Retirement Income Security Act of 1974, except that the reference in paragraph (7) of such section to an “association health plan” shall be deemed a reference to an arrangement referred to in this subsection.

Subtitle E—Health Care Access, Affordability, and Quality Commission

SEC. 141. ESTABLISHMENT OF COMMISSION.

Part 5 of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

“SEC. 518. HEALTH POLICY COMMISSION.

“(a) ESTABLISHMENT.—There is hereby established a commission to be known as the Health Care Access, Af-

1 fordability, and Quality Commission (hereinafter in this
2 Act referred to as the "Commission").

3 “(b) DUTIES OF COMMISSION.—The duties of the
4 Commission shall be as follows:

5 “(1) STUDIES OF CRITICAL AREAS.—Based on
6 information gathered by appropriate Federal agen-
7 cies, advisory groups, and other appropriate sources
8 for health care information, studies, and data, the
9 Commission shall study and report on in each of the
10 following areas:

11 “(A) Independent expert external review
12 programs.

13 “(B) Consumer friendly information pro-
14 grams.

15 “(C) The extent to which the following af-
16 fect patient quality and satisfaction:

17 “(i) health plan enrollees’ attitudes
18 based on surveys;

19 “(ii) outcomes measurements; and

20 “(iii) accreditation by private organi-
21 zations.

22 “(D) Available systems to ensure the time-
23 ly processing of claims.

24 “(2) ESTABLISHMENT OF FORM FOR REMIT-
25 TANCE OF CLAIMS TO PROVIDERS.—Not later than

1 2 years after the date of the first meeting of the
2 Commission, the Commission shall develop and
3 transmit to the Secretary a proposed form for use
4 by health insurance issuers (as defined in section
5 733(b)(2)) for the remittance of claims to health
6 care providers. Effective for plan years beginning
7 after 5 years after the date of the Comprehensive
8 Access and Responsibility in Health Care Act of
9 1999, a health insurance issuer offering health in-
10 surance coverage in connection with a group health
11 plan shall use such form for the remittance of all
12 claims to providers.

13 “(3) EVALUATION OF HEALTH BENEFITS MAN-
14 DATES.—At the request of the chairmen or ranking
15 minority members of the appropriate committees of
16 Congress, the Commission shall evaluate, taking into
17 consideration the overall cost effect, availability of
18 treatment, and the effect on the health of the gen-
19 eral population, existing and proposed benefit re-
20 quirements for group health plans.

21 “(4) COMMENTS ON CERTAIN SECRETARIAL RE-
22 PORTS.—If the Secretary submits to Congress (or a
23 committee of Congress) a report that is required by
24 law and that relates to policies under this section,
25 the Secretary shall transmit a copy of the report to

1 the Commission. The Commission shall review the
2 report and, not later than 6 months after the date
3 of submittal of the Secretary's report to Congress,
4 shall submit to the appropriate committees of Con-
5 gress written comments on such report. Such com-
6 ments may include such recommendations as the
7 Commission deems appropriate.

8 “(5) AGENDA AND ADDITIONAL REVIEW.—The
9 Commission shall consult periodically with the chair-
10 men and ranking minority members of the appro-
11 priate committees of Congress regarding the Com-
12 mission's agenda and progress toward achieving the
13 agenda. The Commission may conduct additional re-
14 views, and submit additional reports to the appro-
15 priate committees of Congress, from time to time on
16 such topics as may be requested by such chairmen
17 and members and as the Commission deems appro-
18 priate.

19 “(6) AVAILABILITY OF REPORTS.—The Com-
20 mission shall transmit to the Secretary a copy of
21 each report submitted under this subsection and
22 shall make such reports available to the public.

23 “(c) MEMBERSHIP.—

1 “(1) NUMBER AND APPOINTMENT.—The Com-
2 mission shall be composed of 11 members appointed
3 by the Comptroller General.

4 “(2) QUALIFICATIONS.—

5 “(A) IN GENERAL.—The membership of
6 the Commission shall include—

7 “(i) physicians and other health pro-
8 fessionals;

9 “(ii) representatives of employers, in-
10 cluding multiemployer plans;

11 “(ii) representatives of insured em-
12 ployees;

13 “(iv) third-party payers; and

14 “(v) health services and health eco-
15 nomics researchers with expertise in out-
16 comes and effectiveness research and tech-
17 nology assessment.

18 “(B) ETHICAL DISCLOSURE.—The Comp-
19 troller General shall establish a system for pub-
20 lic disclosure by members of the Commission of
21 financial and other potential conflicts of interest
22 relating to such members.

23 “(3) TERMS.—

24 “(A) IN GENERAL.—Each member shall be
25 appointed for a term of 3 years, except that the

1 Comptroller shall designate staggered terms for
2 the members first appointed.

3 “(B) VACANCIES.—Any member appointed
4 to fill a vacancy occurring before the expiration
5 of the term for which the member’s predecessor
6 was appointed shall be appointed only for the
7 remainder of that term. A member may serve
8 after the expiration of that member’s term until
9 a successor has taken office. A vacancy in the
10 Commission shall be filled in the manner in
11 which the original appointment was made.

12 “(4) BASIC PAY.—

13 “(A) RATES OF PAY.—Except as provided
14 in subparagraph (B), members shall each be
15 paid at a rate equal to the rate of basic pay
16 payable for level IV of the Executive Schedule
17 for each day (including travel time) during
18 which they are engaged in the actual perform-
19 ance of duties vested in the Commission.

20 “(B) PROHIBITION OF COMPENSATION OF
21 FEDERAL EMPLOYEES.—Members of the Com-
22 mission who are full-time officers or employees
23 of the United States (or Members of Congress)
24 may not receive additional pay, allowances, or

benefits by reason of their service on the Commission.

“(5) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with sections 5702 and 5703 of title 5, United States Code.

“(6) CHAIRPERSON.—The Chairperson of the Commission shall be designated by the Comptroller at the time of the appointment. The term of office of the Chairperson shall be 3 years.

“(7) MEETINGS.—The Commission shall meet 4 times each year.

“(d) DIRECTOR AND STAFF OF COMMISSION.—

“(1) DIRECTOR.—The Commission shall have a Director who shall be appointed by the Chairperson. The Director shall be paid at a rate not to exceed the maximum rate of basic pay payable for GS-13 of the General Schedule.

“(2) STAFF.—The Director may appoint 2 additional staff members.

“(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The Director and staff of the Commission shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in ac-

1 cordance with the provisions of chapter 51 and sub-
2 chapter III of chapter 53 of that title relating to
3 classification and General Schedule pay rates.

4 “(e) POWERS OF COMMISSION.—

5 “(1) HEARINGS AND SESSIONS.—The Commis-
6 sion may, for the purpose of carrying out this Act,
7 hold hearings, sit and act at times and places, take
8 testimony, and receive evidence as the Commission
9 considers appropriate. The Commission may admin-
10 ister oaths or affirmations to witnesses appearing
11 before it.

12 “(2) POWERS OF MEMBERS AND AGENTS.—Any
13 member or agent of the Commission may, if author-
14 ized by the Commission, take any action which the
15 Commission is authorized to take by this section.

16 “(3) OBTAINING OFFICIAL DATA.—The Com-
17 mission may secure directly from any department or
18 agency of the United States information necessary
19 to enable it to carry out this Act. Upon request of
20 the Chairperson of the Commission, the head of that
21 department or agency shall furnish that information
22 to the Commission.

23 “(4) MAILS.—The Commission may use the
24 United States mails in the same manner and under

1 the same conditions as other departments and agen-
2 cies of the United States.

3 “(5) ADMINISTRATIVE SUPPORT SERVICES.—

4 Upon the request of the Commission, the Adminis-
5 trator of General Services shall provide to the Com-
6 mission, on a reimbursable basis, the administrative
7 support services necessary for the Commission to
8 carry out its responsibilities under this Act.

9 “(6) CONTRACT AUTHORITY.—The Commission

10 may contract with and compensate government and
11 private agencies or persons for services, without re-
12 gard to section 3709 of the Revised Statutes (41
13 U.S.C. 5).

14 “(f) REPORTS.—Beginning December 31, 2000, and

15 each year thereafter, the Commission shall submit to the
16 Congress an annual report detailing the following informa-
17 tion:

18 “(1) Access to care, affordability to employers
19 and employees, and quality of care under employer-
20 sponsored health plans and recommendations for im-
21 proving such access, affordability, and quality.

22 “(2) Any issues the Commission deems appro-
23 priate or any issues (such as the appropriateness
24 and availability of particular medical treatment) that
25 the chairmen or ranking members of the appropriate

1 committees of Congress requested the Commission
2 to evaluate.

3 “(g) DEFINITION OF APPROPRIATE COMMITTEES OF
4 CONGRESS.—For purposes of this section the term ‘appro-
5 priate committees of Congress’ means any committee in
6 the Senate or House of Representatives having jurisdiction
7 over the Employee Retirement Income Security Act of
8 1974.

9 “(h) TERMINATION.—Section 14(a)(2)(B) of the
10 Federal Advisory Committee Act (5 U.S.C. App.; relating
11 to the termination of advisory committees) shall not apply
12 to the Commission.

13 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is
14 authorized to be appropriated for fiscal years 2000
15 through 2004 such sums as may be necessary to carry
16 out this section.”.

17 **SEC. 142. EFFECTIVE DATE.**

18 This subtitle shall be effective 6 months after the
19 date of the enactment of this Act.

1 **TITLE II—AMENDMENTS TO THE**
2 **PUBLIC HEALTH SERVICE ACT**
3 **Subtitle A—Patient Protections**
4 **and Point of Service Coverage**
5 **Requirements**

6 **SEC. 201. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
7 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
8 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
9 **ATRIC CARE, AND CONTINUITY OF CARE.**

10 (a) IN GENERAL.—Subpart 2 of part A of title
11 XXVII of the Public Health Service Act is amended by
12 adding at the end the following new section:

13 **“SEC. 2707. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
14 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
15 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
16 **ATRIC CARE, AND CONTINUITY OF CARE.**

17 **“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
18 **ADVICE.—**

19 **“(1) IN GENERAL.—**In the case of any health
20 care professional acting within the lawful scope of
21 practice in the course of carrying out a contractual
22 employment arrangement or other direct contractual
23 arrangement between such professional and a group
24 health plan or a health insurance issuer offering
25 health insurance coverage in connection with a group

1 health plan, the plan or issuer with which such con-
2 tractual employment arrangement or other direct
3 contractual arrangement is maintained by the pro-
4 fessional may not impose on such professional under
5 such arrangement any prohibition or restriction with
6 respect to advice, provided to a participant or bene-
7 ficiary under the plan who is a patient, about the
8 health status of the participant or beneficiary or the
9 medical care or treatment for the condition or dis-
10 ease of the participant or beneficiary, regardless of
11 whether benefits for such care or treatment are pro-
12 vided under the plan or health insurance coverage
13 offered in connection with the plan.

14 “(2) HEALTH CARE PROFESSIONAL DEFINED.—

15 For purposes of this paragraph, the term ‘health
16 care professional’ means a physician (as defined in
17 section 1861(r) of the Social Security Act) or other
18 health care professional if coverage for the profes-
19 sional’s services is provided under the group health
20 plan for the services of the professional. Such term
21 includes a podiatrist, optometrist, chiropractor, psy-
22 chologist, dentist, physician assistant, physical or oc-
23 cupational therapist and therapy assistant, speech-
24 language pathologist, audiologist, registered or li-
25 censed practical nurse (including nurse practitioner,

1 clinical nurse specialist, certified registered nurse
2 anesthetist, and certified nurse-midwife), licensed
3 certified social worker, registered respiratory thera-
4 pist, and certified respiratory therapy technician.

5 “(3) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to require the
7 sponsor of a group health plan or a health insurance
8 issuer offering health insurance coverage in connec-
9 tion with the group health plan to engage in any
10 practice that would violate its religious beliefs or
11 moral convictions.

12 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
13 CARE.—

14 “(1) COVERAGE OF EMERGENCY SERVICES.—

15 “(A) IN GENERAL.—If a group health
16 plan, or health insurance coverage offered by a
17 health insurance issuer, provides any benefits
18 with respect to emergency services (as defined
19 in subparagraph (B)(ii)), or ambulance services,
20 the plan or issuer shall cover emergency serv-
21 ices (including emergency ambulance services as
22 defined in subparagraph (B)(iii)) furnished
23 under the plan or coverage—

24 “(i) without the need for any prior
25 authorization determination;

1 “(ii) whether or not the health care
2 provider furnishing such services is a par-
3 ticipating provider with respect to such
4 services;

5 “(iii) in a manner so that, if such
6 services are provided to a participant, ben-
7 eficiary, or enrollee by a nonparticipating
8 health care provider, the participant, bene-
9 ficiary, or enrollee is not liable for amounts
10 that exceed the amounts of liability that
11 would be incurred if the services were pro-
12 vided by a participating provider; and

13 “(iv) without regard to any other term
14 or condition of such plan or coverage
15 (other than exclusion or coordination of
16 benefits, or an affiliation or waiting period,
17 permitted under section 2701 and other
18 than applicable cost sharing).

19 “(B) DEFINITIONS.—In this subsection:

20 “(i) EMERGENCY MEDICAL CONDI-
21 TION.—The term ‘emergency medical con-
22 dition’ means—

23 “(I) a medical condition mani-
24 festing itself by acute symptoms of
25 sufficient severity (including severe

1 pain) such that a prudent layperson,
2 who possesses an average knowledge
3 of health and medicine, could reason-
4 ably expect the absence of immediate
5 medical attention to result in a condi-
6 tion described in clause (i), (ii), or
7 (iii) of section 1867(e)(1)(A) of the
8 Social Security Act (42 U.S.C.
9 1395dd(e)(1)(A)); and

10 “(II) a medical condition mani-
11 festing itself in a neonate by acute
12 symptoms of sufficient severity (in-
13 cluding severe pain) such that a pru-
14 dent health care professional could
15 reasonably expect the absence of im-
16 mediate medical attention to result in
17 a condition described in clause (i),
18 (ii), or (iii) of section 1867(e)(1)(A)
19 of the Social Security Act.

20 “(ii) EMERGENCY SERVICES.—The
21 term ‘emergency services’ means—

22 “(I) with respect to an emer-
23 gency medical condition described in
24 clause (i)(I), a medical screening ex-
25 amination (as required under section

1 1867 of the Social Security Act, 42
2 U.S.C. 1395dd)) that is within the ca-
3 pability of the emergency department
4 of a hospital, including ancillary serv-
5 ices routinely available to the emer-
6 gency department to evaluate an
7 emergency medical condition (as de-
8 fined in clause (i)) and also, within
9 the capabilities of the staff and facili-
10 ties at the hospital, such further med-
11 ical examination and treatment as are
12 required under section 1867 of such
13 Act to stabilize the patient; or

14 “(II) with respect to an emer-
15 gency medical condition described in
16 clause (i)(II), medical treatment for
17 such condition rendered by a health
18 care provider in a hospital to a
19 neonate, including available hospital
20 ancillary services in response to an ur-
21 gent request of a health care profes-
22 sional and to the extent necessary to
23 stabilize the neonate.

24 “(iii) EMERGENCY AMBULANCE SERV-
25 ICES.—The term ‘emergency ambulance

1 services' means ambulance services (as de-
2 fined for purposes of section 1861(s)(7) of
3 the Social Security Act) furnished to trans-
4 port an individual who has an emergency
5 medical condition (as defined in clause (i))
6 to a hospital for the receipt of emergency
7 services (as defined in clause (ii)) in a case
8 in which appropriate emergency medical
9 screening examinations are covered under
10 the plan or coverage pursuant to para-
11 graph (1)(A) and a prudent layperson,
12 with an average knowledge of health and
13 medicine, could reasonably expect that the
14 absence of such transport would result in
15 placing the health of the individual in seri-
16 ous jeopardy, serious impairment of bodily
17 function, or serious dysfunction of any
18 bodily organ or part.

19 “(iv) STABILIZE.—The term ‘to sta-
20 bilize’ means, with respect to an emergency
21 medical condition, to provide such medical
22 treatment of the condition as may be nec-
23 essary to assure, within reasonable medical
24 probability, that no material deterioration
25 of the condition is likely to result from or

1 occur during the transfer of the individual
2 from a facility.

3 “(v) NONPARTICIPATING.—The term
4 ‘nonparticipating’ means, with respect to a
5 health care provider that provides health
6 care items and services to a participant or
7 beneficiary under group health plan or
8 under group health insurance coverage, a
9 health care provider that is not a partici-
10 pating health care provider with respect to
11 such items and services.

12 “(vi) PARTICIPATING.—The term
13 ‘participating’ means, with respect to a
14 health care provider that provides health
15 care items and services to a participant or
16 beneficiary under group health plan or
17 health insurance coverage offered by a
18 health insurance issuer in connection with
19 such a plan, a health care provider that
20 furnishes such items and services under a
21 contract or other arrangement with the
22 plan or issuer.

23 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
24 LOGICAL CARE.—

1 “(1) IN GENERAL.—In any case in which a
2 group health plan (or a health insurance issuer of-
3 fering health insurance coverage in connection with
4 the plan)—

5 “(A) provides benefits under the terms of
6 the plan consisting of—

7 “(i) gynecological care (such as pre-
8 ventive women’s health examinations); or

9 “(ii) obstetric care (such as preg-
10 nancy-related services),

11 provided by a participating health care profes-
12 sional who specializes in such care (or provides
13 benefits consisting of payment for such care);
14 and

15 “(B) requires or provides for designation
16 by a participant or beneficiary of a partici-
17 pating primary care provider,
18 if the primary care provider designated by such a
19 participant or beneficiary is not such a health care
20 professional, then the plan (or issuer) shall meet the
21 requirements of paragraph (2).

22 “(2) REQUIREMENTS.—A group health plan (or
23 a health insurance issuer offering health insurance
24 coverage in connection with the plan) meets the re-
25 quirements of this paragraph, in connection with

1 benefits described in paragraph (1) consisting of
2 care described in clause (i) or (ii) of paragraph
3 (1)(A) (or consisting of payment therefor), if the
4 plan (or issuer)—

5 “(A) does not require authorization or a
6 referral by the primary care provider in order
7 to obtain such benefits; and

8 “(B) treats the ordering of other care of
9 the same type, by the participating health care
10 professional providing the care described in
11 clause (i) or (ii) of paragraph (1)(A), as the au-
12 thorization of the primary care provider with
13 respect to such care.

14 “(3) HEALTH CARE PROFESSIONAL DEFINED.—
15 For purposes of this subsection, the term ‘health
16 care professional’ means an individual (including,
17 but not limited to, a nurse midwife or nurse practi-
18 tioner) who is licensed, accredited, or certified under
19 State law to provide obstetric and gynecological
20 health care services and who is operating within the
21 scope of such licensure, accreditation, or certifi-
22 cation.

23 “(4) CONSTRUCTION.—Nothing in paragraph
24 (1) shall be construed as preventing a plan from of-
25 fering (but not requiring a participant or beneficiary

1 to accept) a health care professional trained,
2 credentialed, and operating within the scope of their
3 licensure to perform obstetric and gynecological
4 health care services. Nothing in paragraph (2)(B)
5 shall waive any requirements of coverage relating to
6 medical necessity or appropriateness with respect to
7 coverage of gynecological or obstetric care so or-
8 dered.

9 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
10 TIONS.—In the case of a plan providing benefits
11 under two or more coverage options, the require-
12 ments of this subsection shall apply separately with
13 respect to each coverage option.

14 “(d) PATIENT RIGHT TO PEDIATRIC CARE.—

15 “(1) IN GENERAL.—In any case in which a
16 group health plan (or a health insurance issuer of-
17 fering health insurance coverage in connection with
18 the plan) provides benefits consisting of routine pe-
19 diatric care provided by a participating health care
20 professional who specializes in pediatrics (or con-
21 sisting of payment for such care) and the plan re-
22 quires or provides for designation by a participant or
23 beneficiary of a participating primary care provider,
24 the plan (or issuer) shall provide that such a partici-
25 pating health care professional may be designated, if

1 available, by a parent or guardian of any beneficiary
2 under the plan who is under 18 years of age, as
3 the primary care provider with respect to any such
4 benefits.

5 “(2) HEALTH CARE PROFESSIONAL DEFINED.—
6 For purposes of this subsection, the term ‘health
7 care professional’ means an individual who is li-
8 censed, accredited, or certified under State law to
9 provide pediatric health care services and who is op-
10 erating within the scope of such licensure, accredita-
11 tion, or certification.

12 “(3) CONSTRUCTION.—Nothing in paragraph
13 (1) shall be construed as preventing a plan from of-
14 fering (but not requiring a participant or beneficiary
15 to accept) a health care professional trained,
16 credentialed, and operating within the scope of their
17 licensure to perform pediatric health care services.
18 Nothing in paragraph (1) shall waive any require-
19 ments of coverage relating to medical necessity or
20 appropriateness with respect to coverage of pediatric
21 care so ordered.

22 “(4) TREATMENT OF MULTIPLE COVERAGE OP-
23 TIONS.—In the case of a plan providing benefits
24 under two or more coverage options, the require-

ments of this subsection shall apply separately with respect to each coverage option.

“(e) CONTINUITY OF CARE.—

“(1) IN GENERAL.—

“(A) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, and a health care provider is terminated (as defined in subparagraph (D)(ii)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who, at the time of such termination, is a participant or beneficiary in the plan and is scheduled to undergo surgery (including an organ transplantation), is undergoing treatment for pregnancy, or is determined to be terminally ill (as defined in section 1861(dd)(3)(A) of the Social Security Act) and is undergoing treatment for the terminal illness, the plan or issuer shall—

“(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treat-

1 ment by the provider under this sub-
2 section; and

3 “(ii) subject to paragraph (3), permit
4 the individual to elect to continue to be
5 covered with respect to treatment by the
6 provider for such surgery, pregnancy, or
7 illness during a transitional period (pro-
8 vided under paragraph (2)).

9 “(B) TREATMENT OF TERMINATION OF
10 CONTRACT WITH HEALTH INSURANCE
11 ISSUER.—If a contract for the provision of
12 health insurance coverage between a group
13 health plan and a health insurance issuer is ter-
14 minated and, as a result of such termination,
15 coverage of services of a health care provider is
16 terminated with respect to an individual, the
17 provisions of subparagraph (A) (and the suc-
18 ceeding provisions of this subsection) shall
19 apply under the plan in the same manner as if
20 there had been a contract between the plan and
21 the provider that had been terminated, but only
22 with respect to benefits that are covered under
23 the plan after the contract termination.

24 “(C) TERMINATION DEFINED.—For pur-
25 poses of this subsection, the term ‘terminated’

1 includes, with respect to a contract, the expira-
2 tion or nonrenewal of the contract, but does not
3 include a termination of the contract by the
4 plan or issuer for failure to meet applicable
5 quality standards or for fraud.

6 “(2) TRANSITIONAL PERIOD.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraphs (B) through (D), the transi-
9 tional period under this paragraph shall extend
10 up to 90 days (as determined by the treating
11 health care professional) after the date of the
12 notice described in paragraph (1)(A)(i) of the
13 provider’s termination.

14 “(B) SCHEDULED SURGERY.—If surgery
15 was scheduled for an individual before the date
16 of the announcement of the termination of the
17 provider status under paragraph (1)(A)(i), the
18 transitional period under this paragraph with
19 respect to the surgery shall extend beyond the
20 period under subparagraph (A) and until the
21 date of discharge of the individual after comple-
22 tion of the surgery.

23 “(C) PREGNANCY.—If—

24 “(i) a participant or beneficiary was
25 determined to be pregnant at the time of

1 a provider's termination of participation,
2 and

3 “(ii) the provider was treating the
4 pregnancy before date of the termination,
5 the transitional period under this paragraph
6 with respect to provider's treatment of the
7 pregnancy shall extend through the provision of
8 post-partum care directly related to the deliv-
9 ery.

10 “(D) TERMINAL ILLNESS.—If—

11 “(i) a participant or beneficiary was
12 determined to be terminally ill (as deter-
13 mined under section 1861(dd)(3)(A) of the
14 Social Security Act) at the time of a pro-
15 vider's termination of participation, and

16 “(ii) the provider was treating the ter-
17 minal illness before the date of termi-
18 nation,

19 the transitional period under this paragraph
20 shall extend for the remainder of the individ-
21 ual's life for care directly related to the treat-
22 ment of the terminal illness or its medical
23 manifestations.

24 “(3) PERMISSIBLE TERMS AND CONDITIONS.—

25 A group health plan or health insurance issuer may

1 condition coverage of continued treatment by a pro-
2 vider under paragraph (1)(A)(i) upon the individual
3 notifying the plan of the election of continued cov-
4 erage and upon the provider agreeing to the fol-
5 lowing terms and conditions:

6 “(A) The provider agrees to accept reim-
7 bursement from the plan or issuer and indi-
8 vidual involved (with respect to cost-sharing) at
9 the rates applicable prior to the start of the
10 transitional period as payment in full (or, in the
11 case described in paragraph (1)(B), at the rates
12 applicable under the replacement plan or issuer
13 after the date of the termination of the contract
14 with the health insurance issuer) and not to im-
15 pose cost-sharing with respect to the individual
16 in an amount that would exceed the cost-shar-
17 ing that could have been imposed if the contract
18 referred to in paragraph (1)(A) had not been
19 terminated.

20 “(B) The provider agrees to adhere to the
21 quality assurance standards of the plan or
22 issuer responsible for payment under subpara-
23 graph (A) and to provide to such plan or issuer
24 necessary medical information related to the
25 care provided.

1 “(C) The provider agrees otherwise to ad-
2 here to such plan’s or issuer’s policies and pro-
3 cedures, including procedures regarding refer-
4 rals and obtaining prior authorization and pro-
5 viding services pursuant to a treatment plan (if
6 any) approved by the plan or issuer.

7 “(D) The provider agrees to provide tran-
8 sitional care to all participants and beneficiaries
9 who are eligible for and elect to have coverage
10 of such care from such provider.

11 “(E) If the provider initiates the termi-
12 nation, the provider has notified the plan within
13 30 days prior to the effective date of the termi-
14 nation of—

15 “(i) whether the provider agrees to
16 permissible terms and conditions (as set
17 forth in this paragraph) required by the
18 plan, and

19 “(ii) if the provider agrees to the
20 terms and conditions, the specific plan
21 beneficiaries and participants undergoing a
22 course of treatment from the provider who
23 the provider believes, at the time of the no-
24 tification, would be eligible for transitional
25 care under this subsection.

1 “(4) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed to—

3 “(A) require the coverage of benefits which
4 would not have been covered if the provider in-
5 volved remained a participating provider, or

6 “(B) prohibit a group health plan from
7 conditioning a provider’s participation on the
8 provider’s agreement to provide transitional
9 care to all participants and beneficiaries eligible
10 to obtain coverage of such care furnished by the
11 provider as set forth under this subsection.

12 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
13 APPROVED CANCER CLINICAL TRIALS.—

14 “(1) COVERAGE.—

15 “(A) IN GENERAL.—If a group health plan
16 (or a health insurance issuer offering health in-
17 surance coverage) provides coverage to a quali-
18 fied individual (as defined in paragraph (2)),
19 the plan or issuer—

20 “(i) may not deny the individual par-
21 ticipation in the clinical trial referred to in
22 paragraph (2)(B);

23 “(ii) subject to paragraphs (2), (3),
24 and (4), may not deny (or limit or impose
25 additional conditions on) the coverage of

1 routine patient costs for items and services
2 furnished in connection with participation
3 in the trial; and

4 “(iii) may not discriminate against the
5 individual on the basis of the participation
6 of the participant or beneficiary in such
7 trial.

8 “(B) EXCLUSION OF CERTAIN COSTS.—
9 For purposes of subparagraph (A)(ii), routine
10 patient costs do not include the cost of the tests
11 or measurements conducted primarily for the
12 purpose of the clinical trial involved.

13 “(C) USE OF IN-NETWORK PROVIDERS.—If
14 one or more participating providers is partici-
15 pating in a clinical trial, nothing in subpara-
16 graph (A) shall be construed as preventing a
17 plan from requiring that a qualified individual
18 participate in the trial through such a partici-
19 pating provider if the provider will accept the
20 individual as a participant in the trial.

21 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
22 purposes of paragraph (1), the term ‘qualified indi-
23 vidual’ means an individual who is a participant or
24 beneficiary in a group health plan and who meets
25 the following conditions:

1 “(A)(i) The individual has been diagnosed
2 with cancer.

3 “(ii) The individual is eligible to partici-
4 pate in an approved clinical trial according to
5 the trial protocol with respect to treatment of
6 cancer.

7 “(iii) The individual’s participation in the
8 trial offers meaningful potential for significant
9 clinical benefit for the individual.

10 “(B) Either—

11 “(i) the referring physician is a par-
12 ticipating health care professional and has
13 concluded that the individual’s participa-
14 tion in such trial would be appropriate
15 based upon satisfaction by the individual of
16 the conditions described in subparagraph
17 (A); or

18 “(ii) the individual provides medical
19 and scientific information establishing that
20 the individual’s participation in such trial
21 would be appropriate based upon the satis-
22 faction by the individual of the conditions
23 described in subparagraph (A).

24 “(3) PAYMENT.—

1 “(A) IN GENERAL.—A group health plan
2 (or a health insurance issuer offering health in-
3 surance coverage) shall provide for payment for
4 routine patient costs described in paragraph
5 (1)(B) but is not required to pay for costs of
6 items and services that are reasonably expected
7 to be paid for by the sponsors of an approved
8 clinical trial.

9 “(B) ROUTINE PATIENT CARE COSTS.—

10 “(i) IN GENERAL.—For purposes of
11 this paragraph, the term ‘routine patient
12 care costs’ shall include the costs associ-
13 ated with the provision of items and serv-
14 ices that—

15 “(I) would otherwise be covered
16 under the group health plan if such
17 items and services were not provided
18 in connection with an approved clin-
19 ical trial program; and

20 “(II) are furnished according to
21 the protocol of an approved clinical
22 trial program.

23 “(ii) EXCLUSION.—For purposes of
24 this paragraph, ‘routine patient care costs’

1 shall not include the costs associated with
2 the provision of—

3 “(I) an investigational drug or
4 device, unless the Secretary has au-
5 thorized the manufacturer of such
6 drug or device to charge for such drug
7 or device; or

8 “(II) any item or service supplied
9 without charge by the sponsor of the
10 approved clinical trial program.

11 “(C) PAYMENT RATE.—For purposes of
12 this subsection—

13 “(i) PARTICIPATING PROVIDERS.—In
14 the case of covered items and services pro-
15 vided by a participating provider, the pay-
16 ment rate shall be at the agreed upon rate.

17 “(ii) NONPARTICIPATING PRO-
18 VIDERS.—In the case of covered items and
19 services provided by a nonparticipating
20 provider, the payment rate shall be at the
21 rate the plan would normally pay for com-
22 parable items or services under clause (i).

23 “(4) APPROVED CLINICAL TRIAL DEFINED.—

24 “(A) IN GENERAL.—For purposes of this
25 subsection, the term ‘approved clinical trial’

1 means a cancer clinical research study or can-
2 cer clinical investigation approved by an Institu-
3 tional Review Board.

4 “(B) CONDITIONS FOR DEPARTMENTS.—

5 The conditions described in this paragraph, for
6 a study or investigation conducted by a Depart-
7 ment, are that the study or investigation has
8 been reviewed and approved through a system
9 of peer review that the Secretary determines—

10 “(i) to be comparable to the system of

11 peer review of studies and investigations
12 used by the National Institutes of Health,
13 and

14 “(ii) assures unbiased review of the

15 highest scientific standards by qualified in-
16 dividuals who have no interest in the out-
17 come of the review.

18 “(5) CONSTRUCTION.—Nothing in this sub-

19 section shall be construed to limit a plan’s coverage
20 with respect to clinical trials.

21 “(6) PLAN SATISFACTION OF CERTAIN RE-
22 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

23 “(A) IN GENERAL.—For purposes of this

24 subsection, insofar as a group health plan pro-
25 vides benefits in the form of health insurance

1 coverage through a health insurance issuer, the
2 plan shall be treated as meeting the require-
3 ments of this subsection with respect to such
4 benefits and not be considered as failing to
5 meet such requirements because of a failure of
6 the issuer to meet such requirements so long as
7 the plan sponsor or its representatives did not
8 cause such failure by the issuer.

9 “(B) CONSTRUCTION.—Nothing in this
10 subsection shall be construed to affect or mod-
11 ify the responsibilities of the fiduciaries of a
12 group health plan under part 4 of subtitle B of
13 title I of the Employee Retirement Income Se-
14 curity Act of 1974.

15 “(7) STUDY AND REPORT.—

16 “(A) STUDY.—The Secretary shall analyze
17 cancer clinical research and its cost implications
18 for managed care, including differentiation in—

19 “(i) the cost of patient care in trials
20 versus standard care;

21 “(ii) the cost effectiveness achieved in
22 different sites of service;

23 “(iii) research outcomes;

24 “(iv) volume of research subjects
25 available in different sites of service;

1 “(v) access to research sites and clin-
2 ical trials by cancer patients;

3 “(vi) patient cost sharing or copay-
4 ment costs realized in different sites of
5 service;

6 “(vii) health outcomes experienced in
7 different sites of service;

8 “(viii) long term health care services
9 and costs experienced in different sites of
10 service;

11 “(ix) morbidity and mortality experi-
12 enced in different sites of service; and

13 “(x) patient satisfaction and pref-
14 erence of sites of service.

15 “(B) REPORT TO CONGRESS.—Not later
16 than January 1, 2005, the Secretary shall sub-
17 mit a report to Congress that contains—

18 “(i) an assessment of any incremental
19 cost to group health plans resulting from
20 the provisions of this section;

21 “(ii) a projection of expenditures to
22 such plans resulting from this section;

23 “(iii) an assessment of any impact on
24 premiums resulting from this section; and

“(iv) recommendations regarding action on other diseases.”.

SEC. 202. REQUIRING HEALTH MAINTENANCE ORGANIZATIONS TO OFFER OPTION OF POINT-OF-SERVICE COVERAGE.

Title XXVII of the Public Health Service Act is amended by inserting after section 2713 the following new section:

“SEC. 2714. REQUIRING OFFERING OF OPTION OF POINT-OF-SERVICE COVERAGE.

“(a) REQUIREMENT TO OFFER COVERAGE OPTION TO CERTAIN EMPLOYERS.—Except as provided in subsection (c), any health insurance issuer which—

“(1) is a health maintenance organization (as defined in section 2791(b)(3)); and

“(2) which provides for coverage of services of one or more classes of health care professionals under health insurance coverage offered in connection with a group health plan only if such services are furnished exclusively through health care professionals within such class or classes who are members of a closed panel of health care professionals,

the issuer shall make available to the plan sponsor in connection with such a plan a coverage option which provides for coverage of such services which are furnished through

1 such class (or classes) of health care professionals regard-
2 less of whether or not the professionals are members of
3 such panel.

4 “(b) REQUIREMENT TO OFFER SUPPLEMENTAL COV-
5 ERAGE TO PARTICIPANTS IN CERTAIN CASES.—Except as
6 provided in subsection (c), if a health insurance issuer
7 makes available a coverage option under and described in
8 subsection (a) to a plan sponsor of a group health plan
9 and the sponsor declines to contract for such coverage op-
10 tion, then the issuer shall make available in the individual
11 insurance market to each participant in the group health
12 plan optional separate supplemental health insurance cov-
13 erage in the individual health insurance market which con-
14 sists of services identical to those provided under such cov-
15 erage provided through the closed panel under the group
16 health plan but are furnished exclusively by health care
17 professionals who are not members of such a closed panel.

18 “(c) EXCEPTIONS.—

19 “(1) OFFERING OF NON-PANEL OPTION.—Sub-
20 sections (a) and (b) shall not apply with respect to
21 a group health plan if the plan offers a coverage op-
22 tion that provides coverage for services that may be
23 furnished by a class or classes of health care profes-
24 sionals who are not in a closed panel. This para-

graph shall be applied separately to distinguishable groups of employees under the plan.

“(2) AVAILABILITY OF COVERAGE THROUGH HEALTHMART.—Subsections (a) and (b) shall not apply to a group health plan if the health insurance coverage under the plan is made available through a HealthMart (as defined in section 2801) and if any health insurance coverage made available through the HealthMart provides for coverage of the services of any class of health care professionals other than through a closed panel of professionals.

“(3) RELICENSURE EXEMPTION.—Subsections (a) and (b) shall not apply to a health maintenance organization in a State in any case in which—

“(A) the organization demonstrates to the applicable authority that the organization has made a good faith effort to obtain (but has failed to obtain) a contract between the organization and any other health insurance issuer providing for the coverage option or supplemental coverage described in subsection (a) or (b), as the case may be, within the applicable service area of the organization; and

“(B) the State requires the organization to receive or qualify for a separate license, as an

1 indemnity insurer or otherwise, in order to offer
2 such coverage option or supplemental coverage,
3 respectively.

4 The applicable authority may require that the orga-
5 nization demonstrate that it meets the requirements
6 of the previous sentence no more frequently than
7 once every 2 years.

8 “(4) INCREASED COSTS.—Subsections (a) and
9 (b) shall not apply to a health maintenance organi-
10 zation if the organization demonstrates to the appli-
11 cable authority, in accordance with generally accept-
12 ed actuarial practice, that, on either a prospective or
13 retroactive basis, the premium for the coverage op-
14 tion or supplemental coverage required to be made
15 available under such respective subsection exceeds by
16 more than 1 percent the premium for the coverage
17 consisting of services which are furnished through a
18 closed panel of health care professionals in the class
19 or classes involved. The applicable authority may re-
20 quire that the organization demonstrate such an in-
21 crease no more frequently than once every 2 years.
22 This paragraph shall be applied on an average per
23 enrollee or similar basis.

24 “(5) COLLECTIVE BARGAINING AGREEMENTS.—
25 Subsections (a) and (b) shall not apply in connection

1 with a group health plan if the plan is established
2 or maintained pursuant to one or more collective
3 bargaining agreements.

4 “(6) SMALL ISSUERS.—Subsections (a) and (b)
5 shall not apply in the case of a health insurance
6 issuer with 25,000 or fewer covered lives.

7 “(d) DEFINITIONS.—For purposes of this section:

8 “(1) COVERAGE THROUGH CLOSED PANEL.—
9 Health insurance coverage for a class of health care
10 professionals shall be treated as provided through a
11 closed panel of such professionals only if such cov-
12 erage consists of coverage of items or services con-
13 sisting of professionals services which are reim-
14 bursed for or provided only within a limited network
15 of such professionals.

16 “(2) HEALTH CARE PROFESSIONAL.—The term
17 ‘health care professional’ has the meaning given
18 such term in section 2707(a)(2).”.

19 **SEC. 203. EFFECTIVE DATE AND RELATED RULES.**

20 (a) IN GENERAL.—The amendments made by this
21 title shall apply with respect to plan years beginning on
22 or after January 1 of the second calendar year following
23 the date of the enactment of this Act, except that the Sec-
24 retary of Health and Human Services may issue regula-
25 tions before such date under such amendments. The Sec-

1 retary shall first issue regulations necessary to carry out
2 the amendments made by this title before the effective
3 date thereof.

4 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
5 enforcement action shall be taken, pursuant to the amend-
6 ments made by this title, against a group health plan or
7 health insurance issuer with respect to a violation of a re-
8 quirement imposed by such amendments before the date
9 of issuance of regulations issued in connection with such
10 requirement, if the plan or issuer has sought to comply
11 in good faith with such requirement.

12 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
13 AGREEMENTS.—In the case of a group health plan main-
14 tained pursuant to one or more collective bargaining
15 agreements between employee representatives and one or
16 more employers ratified before the date of the enactment
17 of this Act, the amendments made by this title shall not
18 apply with respect to plan years beginning before the later
19 of—

20 (1) the date on which the last of the collective
21 bargaining agreements relating to the plan termi-
22 nates (determined without regard to any extension
23 thereof agreed to after the date of the enactment of
24 this Act); or

25 (2) January 1, 2002.

1 For purposes of this subsection, any plan amendment
2 made pursuant to a collective bargaining agreement relat-
3 ing to the plan which amends the plan solely to conform
4 to any requirement added by this title shall not be treated
5 as a termination of such collective bargaining agreement.

6 **Subtitle B—Patient Access to** 7 **Information**

8 **SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING**
9 **PLAN COVERAGE, MANAGED CARE PROCE-**
10 **DURES, HEALTH CARE PROVIDERS, AND**
11 **QUALITY OF MEDICAL CARE.**

12 (a) IN GENERAL.—Subpart 2 of part A of title
13 XXVII of the Public Health Service Act (as amended by
14 subtitle A) is amended further by adding at the end the
15 following new section:

16 **“SEC. 2708. DISCLOSURE BY GROUP HEALTH PLANS.**

17 “(a) DISCLOSURE REQUIREMENT.—Each health in-
18 surance issuer offering health insurance coverage in con-
19 nection with a group health plan shall provide the plan
20 administrator on a timely basis with the information nec-
21 essary to enable the administrator to provide participants
22 and beneficiaries with information in a manner and to an
23 extent consistent with the requirements of section 111 of
24 the Employee Retirement Income Security Act of 1974.
25 To the extent that any such issuer provides such informa-

1 tion on a timely basis to plan participants and bene-
2 ficiaries, the requirements of this subsection shall be
3 deemed satisfied in the case of such plan with respect to
4 such information.

5 “(b) PLAN BENEFITS.—The information required
6 under subsection (a) includes the following:

7 “(1) COVERED ITEMS AND SERVICES.—

8 “(A) CATEGORIZATION OF INCLUDED BEN-
9 EFITS.—A description of covered benefits, cat-
10 egorized by—

11 “(i) types of items and services (in-
12 cluding any special disease management
13 program); and

14 “(ii) types of health care professionals
15 providing such items and services.

16 “(B) EMERGENCY MEDICAL CARE.—A de-
17 scription of the extent to which the plan covers
18 emergency medical care (including the extent to
19 which the plan provides for access to urgent
20 care centers), and any definitions provided
21 under the plan for the relevant plan termi-
22 nology referring to such care.

23 “(C) PREVENTATIVE SERVICES.—A de-
24 scription of the extent to which the plan pro-
25 vides benefits for preventative services.

1 “(D) DRUG FORMULARIES.—A description
2 of the extent to which covered benefits are de-
3 termined by the use or application of a drug
4 formulary and a summary of the process for de-
5 termining what is included in such formulary.

6 “(E) COBRA CONTINUATION COV-
7 ERAGE.—A description of the benefits available
8 under the plan pursuant to part 6.

9 “(2) LIMITATIONS, EXCLUSIONS, AND RESTRIC-
10 TIONS ON COVERED BENEFITS.—

11 “(A) CATEGORIZATION OF EXCLUDED
12 BENEFITS.—A description of benefits specifi-
13 cally excluded from coverage, categorized by
14 types of items and services.

15 “(B) UTILIZATION REVIEW AND
16 PREAUTHORIZATION REQUIREMENTS.—Whether
17 coverage for medical care is limited or excluded
18 on the basis of utilization review or
19 preauthorization requirements.

20 “(C) LIFETIME, ANNUAL, OR OTHER PE-
21 RIOD LIMITATIONS.—A description of the cir-
22 cumstances under which, and the extent to
23 which, coverage is subject to lifetime, annual, or
24 other period limitations, categorized by types of
25 benefits.

1 “(D) CUSTODIAL CARE.—A description of
2 the circumstances under which, and the extent
3 to which, the coverage of benefits for custodial
4 care is limited or excluded, and a statement of
5 the definition used by the plan for custodial
6 care.

7 “(E) EXPERIMENTAL TREATMENTS.—
8 Whether coverage for any medical care is lim-
9 ited or excluded because it constitutes an inves-
10 tigational item or experimental treatment or
11 technology, and any definitions provided under
12 the plan for the relevant plan terminology refer-
13 ring to such limited or excluded care.

14 “(F) MEDICAL APPROPRIATENESS OR NE-
15 CESSITY.—Whether coverage for medical care
16 may be limited or excluded by reason of a fail-
17 ure to meet the plan’s requirements for medical
18 appropriateness or necessity, and any defini-
19 tions provided under the plan for the relevant
20 plan terminology referring to such limited or
21 excluded care.

22 “(G) SECOND OR SUBSEQUENT OPIN-
23 IONS.—A description of the circumstances
24 under which, and the extent to which, coverage

1 for second or subsequent opinions is limited or
2 excluded.

3 “(H) SPECIALTY CARE.—A description of
4 the circumstances under which, and the extent
5 to which, coverage of benefits for specialty care
6 is conditioned on referral from a primary care
7 provider.

8 “(I) CONTINUITY OF CARE.—A description
9 of the circumstances under which, and the ex-
10 tent to which, coverage of items and services
11 provided by any health care professional is lim-
12 ited or excluded by reason of the departure by
13 the professional from any defined set of pro-
14 viders.

15 “(J) RESTRICTIONS ON COVERAGE OF
16 EMERGENCY SERVICES.—A description of the
17 circumstances under which, and the extent to
18 which, the plan, in covering emergency medical
19 care furnished to a participant or beneficiary of
20 the plan imposes any financial responsibility de-
21 scribed in subsection (c) on participants or
22 beneficiaries or limits or conditions benefits for
23 such care subject to any other term or condition
24 of such plan.

1 “(3) NETWORK CHARACTERISTICS.—If the plan
2 (or issuer) utilizes a defined set of providers under
3 contract with the plan (or issuer), a detailed list of
4 the names of such providers and their geographic lo-
5 cation, set forth separately with respect to primary
6 care providers and with respect to specialists.

7 “(c) PARTICIPANT’S FINANCIAL RESPONSIBIL-
8 ITIES.—The information required under subsection (a) in-
9 cludes an explanation of—

10 “(1) a participant’s financial responsibility for
11 payment of premiums, coinsurance, copayments,
12 deductibles, and any other charges; and

13 “(2) the circumstances under which, and the
14 extent to which, the participant’s financial responsi-
15 bility described in paragraph (1) may vary, including
16 any distinctions based on whether a health care pro-
17 vider from whom covered benefits are obtained is in-
18 cluded in a defined set of providers.

19 “(d) DISPUTE RESOLUTION PROCEDURES.—The in-
20 formation required under subsection (a) includes a de-
21 scription of the processes adopted by the plan of the type
22 described in section 503 of the Employee Retirement In-
23 come Security Act of 1974, including—

24 “(1) descriptions thereof relating specifically
25 to—

1 “(A) coverage decisions;

2 “(B) internal review of coverage decisions;

3 and

4 “(C) any external review of coverage deci-
5 sions; and

6 “(2) the procedures and time frames applicable
7 to each step of the processes referred to in subpara-
8 graphs (A), (B), and (C) of paragraph (1).

9 “(e) INFORMATION ON PLAN PERFORMANCE.—Any
10 information required under subsection (a) shall include in-
11 formation concerning the number of external reviews of
12 the type described in section 503 of the Employee Retire-
13 ment Income Security Act of 1974 that have been com-
14 pleted during the prior plan year and the number of such
15 reviews in which a recommendation is made for modifica-
16 tion or reversal of an internal review decision under the
17 plan.

18 “(f) INFORMATION INCLUDED WITH ADVERSE COV-
19 ERAGE DECISIONS.—A health insurance issuer offering
20 health insurance coverage in connection with a group
21 health plan shall provide to each participant and bene-
22 ficiary, together with any notification of the participant
23 or beneficiary of an adverse coverage decision, the fol-
24 lowing information:

1 “(1) PREAUTHORIZATION AND UTILIZATION RE-
2 VIEW PROCEDURES.—A description of the basis on
3 which any preauthorization requirement or any utili-
4 zation review requirement has resulted in the ad-
5 verse coverage decision.

6 “(2) PROCEDURES FOR DETERMINING EXCLU-
7 SIONS BASED ON MEDICAL NECESSITY OR ON INVES-
8 TIGATIONAL ITEMS OR EXPERIMENTAL TREAT-
9 MENTS.—If the adverse coverage decision is based
10 on a determination relating to medical necessity or
11 to an investigational item or an experimental treat-
12 ment or technology, a description of the procedures
13 and medically-based criteria used in such decision.

14 “(g) INFORMATION AVAILABLE ON REQUEST.—

15 “(1) ACCESS TO PLAN BENEFIT INFORMATION
16 IN ELECTRONIC FORM.—

17 “(A) IN GENERAL.—A health insurance
18 issuer offering health insurance coverage in
19 connection with a group health plan may, upon
20 written request (made not more frequently than
21 annually), make available to participants and
22 beneficiaries, in a generally recognized elec-
23 tronic format—

1 “(i) the latest summary plan descrip-
2 tion, including the latest summary of ma-
3 terial modifications, and

4 “(ii) the actual plan provisions setting
5 forth the benefits available under the plan,
6 to the extent such information relates to the
7 coverage options under the plan available to the
8 participant or beneficiary. A reasonable charge
9 may be made to cover the cost of providing
10 such information in such generally recognized
11 electronic format. The Secretary may by regula-
12 tion prescribe a maximum amount which will
13 constitute a reasonable charge under the pre-
14 ceding sentence.

15 “(B) ALTERNATIVE ACCESS.—The require-
16 ments of this paragraph may be met by making
17 such information generally available (rather
18 than upon request) on the Internet or on a pro-
19 prietary computer network in a format which is
20 readily accessible to participants and bene-
21 ficiaries.

22 “(2) ADDITIONAL INFORMATION TO BE PRO-
23 VIDED ON REQUEST.—

24 “(A) INCLUSION IN SUMMARY PLAN DE-
25 SCRIPTION OF SUMMARY OF ADDITIONAL IN-

1 FORMATION.—The information required under
2 subsection (a) includes a summary description
3 of the types of information required by this
4 subsection to be made available to participants
5 and beneficiaries on request.

6 “(B) INFORMATION REQUIRED FROM
7 PLANS AND ISSUERS ON REQUEST.—In addition
8 to information otherwise required to be pro-
9 vided under this subsection, a health insurance
10 issuer offering health insurance coverage in
11 connection with a group health plan shall pro-
12 vide the following information to a participant
13 or beneficiary on request:

14 “(i) CARE MANAGEMENT INFORMA-
15 TION.—A description of the circumstances
16 under which, and the extent to which, the
17 plan has special disease management pro-
18 grams or programs for persons with dis-
19 abilities, indicating whether these pro-
20 grams are voluntary or mandatory and
21 whether a significant benefit differential
22 results from participation in such pro-
23 grams.

24 “(ii) INCLUSION OF DRUGS AND
25 BIOLOGICALS IN FORMULARIES.—A state-

ment of whether a specific drug or biological is included in a formulary used to determine benefits under the plan and a description of the procedures for considering requests for any patient-specific waivers.

“(iii) ACCREDITATION STATUS OF HEALTH INSURANCE ISSUERS AND SERVICE PROVIDERS.—A description of the accreditation and licensing status (if any) of each health insurance issuer offering health insurance coverage in connection with the plan and of any utilization review organization utilized by the issuer or the plan, together with the name and address of the accrediting or licensing authority.

“(iv) QUALITY PERFORMANCE MEASURES.—The latest information (if any) maintained by the health insurance issuer relating to quality of performance of the delivery of medical care with respect to coverage options offered under the plan and of health care professionals and facilities providing medical care under the plan.

“(C) INFORMATION REQUIRED FROM HEALTH CARE PROFESSIONALS.—

1 “(i) QUALIFICATIONS, PRIVILEGES,
2 AND METHOD OF COMPENSATION.—Any
3 health care professional treating a partici-
4 pant or beneficiary under a group health
5 plan shall provide to the participant or
6 beneficiary, on request, a description of his
7 or her professional qualifications (including
8 board certification status, licensing status,
9 and accreditation status, if any), privileges,
10 and experience and a general description
11 by category (including salary, fee-for-serv-
12 ice, capitation, and such other categories
13 as may be specified in regulations of the
14 Secretary) of the applicable method by
15 which such professional is compensated in
16 connection with the provision of such med-
17 ical care.

18 “(ii) COST OF PROCEDURES.—Any
19 health care professional who recommends
20 an elective procedure or treatment while
21 treating a participant or beneficiary under
22 a group health plan that requires a partici-
23 pant or beneficiary to share in the cost of
24 treatment shall inform such participant or
25 beneficiary of each cost associated with the

1 procedure or treatment and an estimate of
2 the magnitude of such costs.

3 “(D) INFORMATION REQUIRED FROM
4 HEALTH CARE FACILITIES ON REQUEST.—Any
5 health care facility from which a participant or
6 beneficiary has sought treatment under a group
7 health plan shall provide to the participant or
8 beneficiary, on request, a description of the fa-
9 cility’s corporate form or other organizational
10 form and all forms of licensing and accredita-
11 tion status (if any) assigned to the facility by
12 standard-setting organizations.

13 “(h) ACCESS TO INFORMATION RELEVANT TO THE
14 COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT
15 OR BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition
16 to information otherwise required to be made available
17 under this section, a health insurance issuer offering
18 health insurance coverage in connection with a group
19 health plan shall, upon written request (made not more
20 frequently than annually), make available to a participant
21 (and an employee who, under the terms of the plan, is
22 eligible for coverage but not enrolled) in connection with
23 a period of enrollment the summary plan description for
24 any coverage option under the plan under which the par-
25 ticipant is eligible to enroll and any information described

1 in clauses (i), (ii), (iii), (vi), (vii), and (viii) of subsection
2 (e)(2)(B).

3 “(i) ADVANCE NOTICE OF CHANGES IN DRUG
4 FORMULARIES.—Not later than 30 days before the effec-
5 tive date of any exclusion of a specific drug or biological
6 from any drug formulary under health insurance coverage
7 offered by a health insurance issuer in connection with a
8 group health plan that is used in the treatment of a chron-
9 ic illness or disease, the issuer shall take such actions as
10 are necessary to reasonably ensure that plan participants
11 are informed of such exclusion. The requirements of this
12 subsection may be satisfied—

13 “(1) by inclusion of information in publications
14 broadly distributed by plan sponsors, employers, or
15 employee organizations;

16 “(2) by electronic means of communication (in-
17 cluding the Internet or proprietary computer net-
18 works in a format which is readily accessible to par-
19 ticipants);

20 “(3) by timely informing participants who,
21 under an ongoing program maintained under the
22 plan, have submitted their names for such notifica-
23 tion; or

24 “(4) by any other reasonable means of timely
25 informing plan participants.

1 “(j) DEFINITIONS AND RELATED RULES.—

2 “(1) IN GENERAL.—For purposes of this
3 section—

4 “(A) GROUP HEALTH PLAN.—The term
5 ‘group health plan’ has the meaning provided
6 such term under section 733(a)(1).

7 “(B) MEDICAL CARE.—The term ‘medical
8 care’ has the meaning provided such term
9 under section 733(a)(2).

10 “(C) HEALTH INSURANCE COVERAGE.—
11 The term ‘health insurance coverage’ has the
12 meaning provided such term under section
13 733(b)(1).

14 “(D) HEALTH INSURANCE ISSUER.—The
15 term ‘health insurance issuer’ has the meaning
16 provided such term under section 733(b)(2).

17 “(2) APPLICABILITY ONLY IN CONNECTION
18 WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

19 “(A) IN GENERAL.—The requirements of
20 this section shall apply only in connection with
21 included group health plan benefits.

22 “(B) INCLUDED GROUP HEALTH PLAN
23 BENEFIT.—For purposes of subparagraph (A),
24 the term ‘included group health plan benefit’

1 means a benefit which is not an excepted ben-
2 efit (as defined in section 2791(c)).”.

3 **SEC. 212. REQUIREMENTS FOR TREATMENT OF PRESCRIP-**
4 **TION DRUGS AND MEDICAL DEVICES AS EX-**
5 **PERIMENTAL OR INVESTIGATIONAL.**

6 Subpart 2 of part A of title XXVII of the Public
7 Health Service Act (as amended by 211) is amended fur-
8 ther by adding at the end the following new section:

9 **“SEC. 2709. REQUIREMENTS FOR TREATMENT OF PRE-**
10 **SCRIPTION DRUGS AND MEDICAL DEVICES**
11 **AS EXPERIMENTAL OR INVESTIGATIONAL.**

12 “(a) IN GENERAL.—No use of a prescription drug
13 or medical device shall be considered experimental or in-
14 vestigational in connection with health insurance coverage
15 offered by a health insurance issuer in connection with a
16 group health plan if such use is included in the labeling
17 authorized by the Food and Drug Administration under
18 section 505, 513, or 515 of the Federal Food, Drug, and
19 Cosmetic Act or under section 351 of the Public Health
20 Service Act, unless clinical benefit has not been adequately
21 demonstrated based on analysis of reliable authoritative
22 scientific evidence.

23 “(b) CONSTRUCTION.—Nothing in this section shall
24 be construed as—

1 “(1) requiring a health insurance issuer offer-
2 ing health insurance coverage in connection with a
3 group health plan to provide any coverage of pre-
4 scription drugs or medical devices, or

5 “(2) precluding a health insurance offering
6 health insurance coverage in connection with a group
7 health plan from considering medical devices cleared
8 through premarket notification under section 510(k)
9 of the Federal Food, Drug, and Cosmetic Act as in-
10 vestigational.

11 “(c) DEFINITIONS.—For purposes of this section—

12 “(1) Terms used in this section which are de-
13 fined in section 2791 shall have the meanings pro-
14 vided such terms under such section, respectively.

15 “(2) The term ‘clinical benefit’ means improve-
16 ment in net health outcome (including but not lim-
17 ited to length of life or ability to function) or in any
18 objectively measurable criterion that is reasonably
19 likely to predict clinical benefit to an extent at least
20 equivalent to the extent that is achievable under the
21 usual conditions of medical practice under estab-
22 lished alternatives.

23 “(3) The term ‘reliable authoritative evidence’
24 means well-designed and well-conducted investiga-
25 tions published in peer-reviewed scientific journals.”.

1 **SEC. 213. EFFECTIVE DATE AND RELATED RULES.**

2 (a) IN GENERAL.—The amendments made by section
3 211 shall apply with respect to plan years beginning on
4 or after January 1 of the second calendar year following
5 the date of the enactment of this Act. The Secretary of
6 Labor shall first issue all regulations necessary to carry
7 out the amendments made by this subtitle before such
8 date.

9 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
10 enforcement action shall be taken, pursuant to the amend-
11 ments made by this subtitle, against a health insurance
12 issuer with respect to a violation of a requirement imposed
13 by such amendments before the date of issuance of final
14 regulations issued in connection with such requirement, if
15 the issuer has sought to comply in good faith with such
16 requirement.

17 **Subtitle C—HealthMarts**

18 **SEC. 221. EXPANSION OF CONSUMER CHOICE THROUGH**
19 **HEALTHMARTS.**

20 (a) IN GENERAL.—The Public Health Service Act is
21 amended by adding at the end the following new title:

22 **“TITLE XXVIII—HEALTHMARTS**

23 **“SEC. 2801. DEFINITION OF HEALTHMART.**

24 **“(a) IN GENERAL.—For purposes of this title, the**
25 **term ‘HealthMart’ means a legal entity that meets the fol-**
26 **lowing requirements:**

1 “(1) ORGANIZATION.—The HealthMart is an
2 organization operated under the direction of a board
3 of directors which is composed of representatives of
4 not fewer than 2 from each of the following:

5 “(A) Small employers, if coverage is of-
6 fered through the HealthMart to small employ-
7 ers.

8 “(B) Employees of such small employers.

9 “(C) Individuals (other than those who are
10 employees of employers) who are eligible to par-
11 ticipate in the HealthMart, if coverage is of-
12 fered through HealthMarts for individuals who
13 are not employees of small employers.

14 “(D) Health care providers, which may be
15 physicians, other health care professionals,
16 health care facilities, or any combination there-
17 of.

18 “(E) Entities, such as insurance compa-
19 nies, health maintenance organizations, and li-
20 censed provider-sponsored organizations, that
21 underwrite or administer health benefits cov-
22 erage.

23 “(2) OFFERING HEALTH BENEFITS COV-
24 ERAGE.—

25 “(A) DIFFERENT GROUPS.—

1 “(i) IN GENERAL.—The HealthMart,
2 in conjunction with those health insurance
3 issuers that offer health benefits coverage
4 through the HealthMart, makes available
5 health benefits coverage in the manner de-
6 scribed in subsection (b) to either or both
7 of the following:

8 “(I) All small employers and eli-
9 gible employees of those employers,
10 and the dependents of such employ-
11 ees.

12 “(II) Other individuals (including
13 self-employed individuals), and the de-
14 pendents of such individuals, who are
15 employees of an employer but not in-
16 cluding employees of employers.

17 “(ii) MANNER OF OFFERING.—Such
18 coverage shall be made available in the
19 manner described in subsection (c)(2) at
20 rates (including employer’s and employee’s
21 share, if applicable) that are established by
22 the health insurance issuer on a policy or
23 product specific basis and that may vary
24 only as permissible under State law. A
25 HealthMart is deemed to be a group health

1 plan for purposes of applying section 702
2 of the Employee Retirement Income Secu-
3 rity Act of 1974, section 2702 of this Act,
4 and section 9802(b) of the Internal Rev-
5 enue Code of 1986 (which limit variation
6 among similarly situated individuals of re-
7 quired premiums for health benefits cov-
8 erage on the basis of health status-related
9 factors).

10 “(iii) SEPARATE BOOKS OF BUSI-
11 NESS.—The coverage that is offered to em-
12 ployers (and employees) described in sub-
13 clause (I) of clause (i) need not be the
14 same as that offered to individuals de-
15 scribed in subclause (II) of such clause and
16 the HealthMart shall establish premiums
17 for coverage under each such subclause as
18 a separate book of business.

19 “(B) NONDISCRIMINATION IN COVERAGE
20 OFFERED.—

21 “(i) IN GENERAL.—Subject to clause
22 (ii), if a HealthMart offers coverage in a
23 geographic area (as specified under para-
24 graph (3)(A)) to eligible employees or indi-
25 viduals, the HealthMart shall offer the

1 same coverage to all such employees or in-
2 dividuals in the same geographic area. Sec-
3 tion 2711(a)(1)(B) of this Act limits denial
4 of enrollment of certain eligible individuals
5 under health benefits coverage in the small
6 group market.

7 “(ii) CONSTRUCTION.—Nothing in
8 this title shall be construed as requiring or
9 permitting a health insurance issuer to
10 provide coverage outside the service area of
11 the issuer, as approved under State law.

12 “(C) NO FINANCIAL UNDERWRITING.—The
13 HealthMart provides health benefits coverage
14 only through contracts with health insurance
15 issuers and does not assume insurance risk with
16 respect to such coverage.

17 “(3) GEOGRAPHIC AREAS.—

18 “(A) SPECIFICATION OF GEOGRAPHIC
19 AREAS.—The HealthMart shall specify the geo-
20 graphic area (or areas) in which it makes avail-
21 able health benefits coverage offered by health
22 insurance issuers to employers, or individuals,
23 as the case may be. Any such area shall encom-
24 pass at least one entire county or equivalent
25 area.

1 “(B) MULTISTATE AREAS.—In the case of
2 a HealthMart that serves more than one State,
3 such geographic areas may be areas that in-
4 clude portions of two or more contiguous
5 States.

6 “(C) MULTIPLE HEALTHMARTS PER-
7 MITTED IN SINGLE GEOGRAPHIC AREA.—Noth-
8 ing in this title shall be construed as preventing
9 the establishment and operation of more than
10 one HealthMart in a geographic area or as lim-
11 iting the number of HealthMarts that may op-
12 erate in any area.

13 “(4) PROVISION OF ADMINISTRATIVE SERVICES
14 TO PURCHASERS.—

15 “(A) IN GENERAL.—The HealthMart pro-
16 vides administrative services for purchasers.
17 Such services may include accounting, billing,
18 enrollment information, and employee coverage
19 status reports.

20 “(B) CONSTRUCTION.—Nothing in this
21 subsection shall be construed as preventing a
22 HealthMart from serving as an administrative
23 service organization to any entity.

24 “(5) DISSEMINATION OF INFORMATION.—The
25 HealthMart collects and disseminates (or arranges

1 for the collection and dissemination of) consumer-
2 oriented information on the scope, cost, and enrollee
3 satisfaction of all coverage options offered through
4 the HealthMart to its members and eligible individ-
5 uals. Such information shall be defined by the
6 HealthMart and shall be in a manner appropriate to
7 the type of coverage offered. To the extent prac-
8 ticable, such information shall include information
9 on provider performance, locations and hours of op-
10 eration of providers, outcomes, and similar matters.
11 Nothing in this section shall be construed as pre-
12 venting the dissemination of such information or
13 other information by the HealthMart or by health
14 insurance issuers through electronic or other means.

15 “(6) FILING INFORMATION.—The
16 HealthMart—

17 “(A) files with the applicable Federal au-
18 thority information that demonstrates the
19 HealthMart’s compliance with the applicable re-
20 quirements of this title; or

21 “(B) in accordance with rules established
22 under section 2803(a), files with a State such
23 information as the State may require to dem-
24 onstrate such compliance.

1 “(b) HEALTH BENEFITS COVERAGE REQUIRE-
2 MENTS.—

3 “(1) COMPLIANCE WITH CONSUMER PROTEC-
4 TION REQUIREMENTS.—Any health benefits coverage
5 offered through a HealthMart shall—

6 “(A) be underwritten by a health insurance
7 issuer that—

8 “(i) is licensed (or otherwise regu-
9 lated) under State law,

10 “(ii) meets all applicable State stand-
11 ards relating to consumer protection, sub-
12 ject to section 2802(b), and

13 “(iii) offers the coverage under a con-
14 tract with the HealthMart;

15 “(B) subject to paragraph (2), be approved
16 or otherwise permitted to be offered under
17 State law; and

18 “(C) provide full portability of creditable
19 coverage for individuals who remain members of
20 the same HealthMart notwithstanding that they
21 change the employer through which they are
22 members in accordance with the provisions of
23 the parts 6 and 7 of subtitle B of title I of the
24 Employee Retirement Income Security Act of
25 1974 and titles XXII and XXVII of this Act,

1 so long as both employers are purchasers in the
2 HealthMart, and notwithstanding that they ter-
3 minate such employment, if the HealthMart
4 permits enrollment directly by eligible individ-
5 uals.

6 “(2) ALTERNATIVE PROCESS FOR APPROVAL OF
7 HEALTH BENEFITS COVERAGE IN CASE OF DISCRIMI-
8 NATION OR DELAY.—

9 “(A) IN GENERAL.—The requirement of
10 paragraph (1)(B) shall not apply to a policy or
11 product of health benefits coverage offered in a
12 State if the health insurance issuer seeking to
13 offer such policy or product files an application
14 to waive such requirement with the applicable
15 Federal authority, and the authority deter-
16 mines, based on the application and other evi-
17 dence presented to the authority, that—

18 “(i) either (or both) of the grounds
19 described in subparagraph (B) for approval
20 of the application has been met; and

21 “(ii) the coverage meets the applicable
22 State standards (other than those that
23 have been preempted under section 2802).

24 “(B) GROUNDS.—The grounds described
25 in this subparagraph with respect to a policy or

1 product of health benefits coverage are as fol-
2 lows:

3 “(i) FAILURE TO ACT ON POLICY,
4 PRODUCT, OR RATE APPLICATION ON A
5 TIMELY BASIS.—The State has failed to
6 complete action on the policy or product
7 (or rates for the policy or product) within
8 90 days of the date of the State’s receipt
9 of a substantially complete application. No
10 period before the date of the enactment of
11 this section shall be included in deter-
12 mining such 90-day period.

13 “(ii) DENIAL OF APPLICATION BASED
14 ON DISCRIMINATORY TREATMENT.—The
15 State has denied such an application
16 and—

17 “(I) the standards or review
18 process imposed by the State as a
19 condition of approval of the policy or
20 product imposes either any material
21 requirements, procedures, or stand-
22 ards to such policy or product that
23 are not generally applicable to other
24 policies and products offered or any

1 requirements that are preempted
2 under section 2802; or

3 “(II) the State requires the
4 issuer, as a condition of approval of
5 the policy or product, to offer any pol-
6 icy or product other than such policy
7 or product.

8 “(C) ENFORCEMENT.—In the case of a
9 waiver granted under subparagraph (A) to an
10 issuer with respect to a State, the Secretary
11 may enter into an agreement with the State
12 under which the State agrees to provide for
13 monitoring and enforcement activities with re-
14 spect to compliance of such an issuer and its
15 health insurance coverage with the applicable
16 State standards described in subparagraph
17 (A)(ii). Such monitoring and enforcement shall
18 be conducted by the State in the same manner
19 as the State enforces such standards with re-
20 spect to other health insurance issuers and
21 plans, without discrimination based on the type
22 of issuer to which the standards apply. Such an
23 agreement shall specify or establish mechanisms
24 by which compliance activities are undertaken,
25 while not lengthening the time required to re-

1 view and process applications for waivers under
2 subparagraph (A).

3 “(3) EXAMPLES OF TYPES OF COVERAGE.—The
4 benefits coverage made available through a
5 HealthMart may include, but is not limited to, any
6 of the following if it meets the other applicable re-
7 quirements of this title:

8 “(A) Coverage through a health mainte-
9 nance organization.

10 “(B) Coverage in connection with a pre-
11 ferred provider organization.

12 “(C) Coverage in connection with a li-
13 censed provider-sponsored organization.

14 “(D) Indemnity coverage through an insur-
15 ance company.

16 “(E) Coverage offered in connection with a
17 contribution into a medical savings account or
18 flexible spending account.

19 “(F) Coverage that includes a point-of-
20 service option.

21 “(G) Any combination of such types of
22 coverage.

23 “(4) WELLNESS BONUSES FOR HEALTH PRO-
24 MOTION.—Nothing in this title shall be construed as
25 precluding a health insurance issuer offering health

benefits coverage through a HealthMart from establishing premium discounts or rebates for members or from modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention so long as such programs are agreed to in advance by the HealthMart and comply with all other provisions of this title and do not discriminate among similarly situated members.

“(c) PURCHASERS; MEMBERS; HEALTH INSURANCE ISSUERS.—

“(1) PURCHASERS.—

“(A) IN GENERAL.—Subject to the provisions of this title, a HealthMart shall permit any employer or any individual described in subsection (a)(1)(C), if coverage is offered through the HealthMart for such employer or individual, to contract with the HealthMart for the purchase of health benefits coverage for its employees and dependents of those employees or for the individual (and the individual’s dependents), respectively, and may not vary conditions of eligibility (including premium rates and membership fees) of an employer or individual to be a purchaser.

1 “(B) ROLE OF ASSOCIATIONS, BROKERS,
2 AND LICENSED HEALTH INSURANCE AGENTS.—
3 Nothing in this section shall be construed as
4 preventing an association, broker, licensed
5 health insurance agent, or other entity from as-
6 sisting or representing a HealthMart or employ-
7 ers or individuals from entering into appro-
8 priate arrangements to carry out this title.

9 “(C) EXCLUSIVE NATURE OF CONTRACT.—

10 “(i) IN GENERAL.—Subject to clause
11 (ii), such a contract shall provide that the
12 purchaser agrees not to obtain or sponsor
13 health benefits coverage, on behalf of any
14 eligible employees (and their dependents),
15 other than through the HealthMart.

16 “(ii) EXCEPTION IF NO COVERAGE OF-
17 FERED IN AREA OF RESIDENCES.—Clause
18 (i) shall not apply to an eligible individual
19 who resides in an area for which no cov-
20 erage is offered by any health insurance
21 issuer through the HealthMart.

22 “(iii) NOTHING PRECLUDING INDIVIDUAL
23 EMPLOYEE OPT-OUT.—Nothing in
24 this subparagraph shall be construed as re-
25 quiring an eligible employee of an employer

1 that is a purchaser to obtain health bene-
2 fits coverage through the HealthMart.

3 “(2) MEMBERS.—

4 “(A) IN GENERAL.—

5 “(i) EMPLOYMENT BASED MEMBER-
6 SHIP.—Under rules established to carry
7 out this title, with respect to an employer
8 that has a purchaser contract with a
9 HealthMart, individuals who are employees
10 of the employer may enroll for group
11 health benefits coverage (including cov-
12 erage for dependents of such enrolling em-
13 ployees) offered by a health insurance
14 issuer through the HealthMart.

15 “(ii) INDIVIDUALS.—Under rules es-
16 tablished to carry out this title, with re-
17 spect to an individual who has a purchaser
18 contract with a HealthMart for himself or
19 herself, the individual may enroll for indi-
20 vidual health benefits coverage (including
21 coverage for dependents of such individual)
22 offered by a health insurance issuer
23 through the HealthMart. Nothing in this
24 clause shall be construed as requiring a

1 HealthMart to offer coverage to individuals
2 in any geographic area.

3 “(B) NONDISCRIMINATION IN ENROLL-
4 MENT.—A HealthMart may not deny enroll-
5 ment as a member to an individual who is an
6 employee or individual (or dependent of such an
7 employee or individual) eligible to be so enrolled
8 based on health status-related factors, except as
9 may be permitted consistent with section
10 2742(b).

11 “(C) ANNUAL OPEN ENROLLMENT PE-
12 RIOD.—In the case of members enrolled in
13 health benefits coverage offered by a health in-
14 surance issuer through a HealthMart, subject
15 to subparagraph (D), the HealthMart shall pro-
16 vide for an annual open enrollment period of 30
17 days during which such members may change
18 the coverage option in which the members are
19 enrolled.

20 “(D) RULES OF ELIGIBILITY.—Nothing in
21 this paragraph shall preclude a HealthMart
22 from establishing rules of employee or indi-
23 vidual eligibility for enrollment and reenroll-
24 ment of members during the annual open en-
25 rollment period under subparagraph (C). Such

1 rules shall be applied consistently to all pur-
2 chasers and members within the HealthMart
3 and shall not be based in any manner on health
4 status-related factors and may not conflict with
5 sections 2701 and 2702 of this Act.

6 “(3) HEALTH INSURANCE ISSUERS.—

7 “(A) PREMIUM COLLECTION.—The con-
8 tract between a HealthMart and a health insur-
9 ance issuer shall provide, with respect to a
10 member enrolled with health benefits coverage
11 offered by the issuer through the HealthMart,
12 for the payment of the premiums collected by
13 the HealthMart (or the issuer) for such cov-
14 erage (less a pre-determined administrative
15 charge negotiated by the HealthMart and the
16 issuer) to the issuer.

17 “(B) SCOPE OF SERVICE AREA.—Nothing
18 in this title shall be construed as requiring the
19 service area of a health insurance issuer with
20 respect to health insurance coverage to cover
21 the entire geographic area served by a
22 HealthMart.

23 “(C) AVAILABILITY OF COVERAGE OP-
24 TIONS.—A HealthMart shall enter into con-
25 tracts with one or more health insurance issuers

1 in a manner that assures that at least 2 health
2 insurance coverage options are made available
3 in the geographic area specified under sub-
4 section (a)(3)(A).

5 “(d) PREVENTION OF CONFLICTS OF INTEREST.—

6 “(1) FOR BOARDS OF DIRECTORS.—A member
7 of a board of directors of a HealthMart may not
8 serve as an employee or paid consultant to the
9 HealthMart, but may receive reasonable reimburse-
10 ment for travel expenses for purposes of attending
11 meetings of the board or committees thereof.

12 “(2) FOR BOARDS OF DIRECTORS OR EMPLOY-
13 EES.—An individual is not eligible to serve in a paid
14 or unpaid capacity on the board of directors of a
15 HealthMart or as an employee of the HealthMart, if
16 the individual is employed by, represents in any ca-
17 pacity, owns, or controls any ownership interest in
18 an organization from whom the HealthMart receives
19 contributions, grants, or other funds not connected
20 with a contract for coverage through the
21 HealthMart.

22 “(3) EMPLOYMENT AND EMPLOYEE REP-
23 RESENTATIVES.—

24 “(A) IN GENERAL.—An individual who is
25 serving on a board of directors of a HealthMart

1 as a representative described in subparagraph
2 (A) or (B) of section 2801(a)(1) shall not be
3 employed by or affiliated with a health insur-
4 ance issuer or be licensed as or employed by or
5 affiliated with a health care provider.

6 “(B) CONSTRUCTION.—For purposes of
7 subparagraph (A), the term “affiliated” does
8 not include membership in a health benefits
9 plan or the obtaining of health benefits cov-
10 erage offered by a health insurance issuer.

11 “(e) CONSTRUCTION.—

12 “(1) NETWORK OF AFFILIATED
13 HEALTHMARTS.—Nothing in this section shall be
14 construed as preventing one or more HealthMarts
15 serving different areas (whether or not contiguous)
16 from providing for some or all of the following
17 (through a single administrative organization or oth-
18 erwise):

19 “(A) Coordinating the offering of the same
20 or similar health benefits coverage in different
21 areas served by the different HealthMarts.

22 “(B) Providing for crediting of deductibles
23 and other cost-sharing for individuals who are
24 provided health benefits coverage through the

HealthMarts (or affiliated HealthMarts)
after—

“(i) a change of employers through
which the coverage is provided, or

“(ii) a change in place of employment
to an area not served by the previous
HealthMart.

“(2) PERMITTING HEALTHMARTS TO ADJUST
DISTRIBUTIONS AMONG ISSUERS TO REFLECT REL-
ATIVE RISK OF ENROLLEES.—Nothing in this sec-
tion shall be construed as precluding a HealthMart
from providing for adjustments in amounts distrib-
uted among the health insurance issuers offering
health benefits coverage through the HealthMart
based on factors such as the relative health care risk
of members enrolled under the coverage offered by
the different issuers.

**“SEC. 2802. APPLICATION OF CERTAIN LAWS AND REQUIRE-
MENTS.**

“(a) AUTHORITY OF STATES.—Nothing in this sec-
tion shall be construed as preempting State laws relating
to the following:

“(1) The regulation of underwriters of health
coverage, including licensure and solvency require-
ments.

1 “(2) The application of premium taxes and re-
2 quired payments for guaranty funds or for contribu-
3 tions to high-risk pools.

4 “(3) The application of fair marketing require-
5 ments and other consumer protections (other than
6 those specifically relating to an item described in
7 subsection (b)).

8 “(4) The application of requirements relating to
9 the adjustment of rates for health insurance cov-
10 erage.

11 “(b) TREATMENT OF BENEFIT AND GROUPING RE-
12 QUIREMENTS.—State laws insofar as they relate to any
13 of the following are superseded and, except as provided
14 under section 2801(c)(3)(C), shall not apply to health ben-
15 efits coverage made available through a HealthMart:

16 “(1) Benefit requirements for health benefits
17 coverage offered through a HealthMart, including
18 (but not limited to) requirements relating to cov-
19 erage of specific providers, specific services or condi-
20 tions, or the amount, duration, or scope of benefits,
21 but not including requirements to the extent re-
22 quired to implement title XXVII or other Federal
23 law and to the extent the requirement prohibits an
24 exclusion of a specific disease from such coverage.

1 “(2) Requirements (commonly referred to as
2 fictitious group laws) relating to grouping and simi-
3 lar requirements for such coverage to the extent
4 such requirements impede the establishment and op-
5 eration of HealthMarts pursuant to this title.

6 “(3) Any other requirements (including limita-
7 tions on compensation arrangements) that, directly
8 or indirectly, preclude (or have the effect of pre-
9 cluding) the offering of such coverage through a
10 HealthMart, if the HealthMart meets the require-
11 ments of this title.

12 Any State law or regulation relating to the composition
13 or organization of a HealthMart is preempted to the ex-
14 tent the law or regulation is inconsistent with the provi-
15 sions of this title.

16 “(c) APPLICATION OF ERISA FIDUCIARY AND DIS-
17 CLOSURE REQUIREMENTS.—The board of directors of a
18 HealthMart is deemed to be a plan administrator of an
19 employee welfare benefit plan which is a group health plan
20 for purposes of applying parts 1 and 4 of subtitle B of
21 title I of the Employee Retirement Income Security Act
22 of 1974 and those provisions of part 5 of such subtitle
23 which are applicable to enforcement of such parts 1 and
24 4, and the HealthMart shall be treated as such a plan
25 and the enrollees enrolled on the basis of employment shall

1 be treated as participants and beneficiaries for purposes
2 of applying such provisions pursuant to this subsection.

3 “(d) APPLICATION OF ERISA RENEWABILITY PRO-
4 TECTION.—A HealthMart is deemed to be group health
5 plan that is a multiple employer welfare arrangement for
6 purposes of applying section 703 of the Employee Retirement
7 Income Security Act of 1974.

8 “(e) APPLICATION OF RULES FOR NETWORK PLANS
9 AND FINANCIAL CAPACITY.—The provisions of sub-
10 sections (c) and (d) of section 2711 apply to health bene-
11 fits coverage offered by a health insurance issuer through
12 a HealthMart.

13 “(f) CONSTRUCTION RELATING TO OFFERING RE-
14 QUIREMENT.—Nothing in section 2711(a) of this Act or
15 703 of the Employee Retirement Income Security Act of
16 1974 shall be construed as permitting the offering outside
17 the HealthMart of health benefits coverage that is only
18 made available through a HealthMart under this section
19 because of the application of subsection (b).

20 “(g) APPLICATION TO GUARANTEED RENEWABILITY
21 REQUIREMENTS IN CASE OF DISCONTINUATION OF AN
22 ISSUER.—For purposes of applying section 2712 in the
23 case of health insurance coverage offered by a health in-
24 surance issuer through a HealthMart, if the contract be-
25 tween the HealthMart and the issuer is terminated and

1 the HealthMart continues to make available any health in-
2 surance coverage after the date of such termination, the
3 following rules apply:

4 “(1) RENEWABILITY.—The HealthMart shall
5 fulfill the obligation under such section of the issuer
6 renewing and continuing in force coverage by offer-
7 ing purchasers (and members and their dependents)
8 all available health benefits coverage that would oth-
9 erwise be available to similarly-situated purchasers
10 and members from the remaining participating
11 health insurance issuers in the same manner as
12 would be required of issuers under section 2712(e).

13 “(2) APPLICATION OF ASSOCIATION RULES.—
14 The HealthMart shall be considered an association
15 for purposes of applying section 2712(e).

16 “(h) CONSTRUCTION IN RELATION TO CERTAIN
17 OTHER LAWS.—Nothing in this title shall be construed
18 as modifying or affecting the applicability to HealthMarts
19 or health benefits coverage offered by a health insurance
20 issuer through a HealthMart of parts 6 and 7 of subtitle
21 B of title I of the Employee Retirement Income Security
22 Act of 1974 or titles XXII and XXVII of this Act.

23 **“SEC. 2803. ADMINISTRATION.**

24 “(a) IN GENERAL.—The applicable Federal authority
25 shall administer this title and is authorized to issue such

1 regulations as may be required to carry out this title. Such
2 regulations shall promote the active development of
3 Healthmarts and first be issued in final form not later
4 than 6 months after the date of the enactment of this title
5 and shall be subject to Congressional review under the
6 provisions of chapter 8 of title 5, United States Code. The
7 applicable Federal authority shall incorporate the process
8 of 'deemed file and use' with respect to the information
9 filed under section 2801(a)(6)(A) and shall determine
10 whether information filed by a HealthMart demonstrates
11 compliance with the applicable requirements of this title.
12 Such authority shall exercise its authority under this title
13 in a manner that fosters and promotes the development
14 of HealthMarts in order to improve access to health care
15 coverage and services.

16 “(b) PERIODIC REPORTS.—The applicable Federal
17 authority shall submit to Congress a report every 30
18 months, during the 10-year period beginning on the effec-
19 tive date of the rules promulgated by the applicable Fed-
20 eral authority to carry out this title, on the effectiveness
21 of this title in promoting coverage of uninsured individ-
22 uals. Such authority may provide for the production of
23 such reports through one or more contracts with appro-
24 priate private entities.

1 **“SEC. 2804. DEFINITIONS.**

2 “For purposes of this title:

3 “(1) **APPLICABLE FEDERAL AUTHORITY.**—The
4 term ‘applicable Federal authority’ means the Sec-
5 retary of Health and Human Services .

6 “(2) **ELIGIBLE EMPLOYEE OR INDIVIDUAL.**—
7 The term ‘eligible’ means, with respect to an em-
8 ployee or other individual and a HealthMart, an em-
9 ployee or individual who is eligible under section
10 2801(c)(2) to enroll or be enrolled in health benefits
11 coverage offered through the HealthMart.

12 “(3) **EMPLOYER; EMPLOYEE; DEPENDENT.**—
13 Except as the applicable Federal authority may oth-
14 erwise provide, the terms ‘employer’, ‘employee’, and
15 ‘dependent’, as applied to health insurance coverage
16 offered by a health insurance issuer licensed (or oth-
17 erwise regulated) in a State, shall have the meanings
18 applied to such terms with respect to such coverage
19 under the laws of the State relating to such coverage
20 and such an issuer. The term ‘dependent’ may in-
21 clude the spouse and children of the individual in-
22 volved.

23 “(4) **HEALTH BENEFITS COVERAGE.**—The term
24 ‘health benefits coverage’ has the meaning given the
25 term group health insurance coverage in section
26 2791(b)(4).

1 “(5) HEALTH INSURANCE ISSUER.—The term
2 ‘health insurance issuer’ has the meaning given such
3 term in section 2791(b)(2).

4 “(6) HEALTH STATUS-RELATED FACTOR.—The
5 term ‘health status-related factor’ has the meaning
6 given such term in section 2791(d)(9).

7 “(7) HEALTHMART.—The term ‘HealthMart’ is
8 defined in section 2801(a).

9 “(8) MEMBER.—The term ‘member’ means,
10 with respect to a HealthMart, an individual enrolled
11 for health benefits coverage through the HealthMart
12 under section 2801(c)(2).

13 “(9) PURCHASER.—The term ‘purchaser’
14 means, with respect to a HealthMart, an employer
15 or individual that has contracted under section
16 2801(c)(1)(A) with the HealthMart for the purchase
17 of health benefits coverage.

18 “(10) SMALL EMPLOYER.—The term ‘small em-
19 ployer’ has the meaning given such term in section
20 2791(e)(4), but also includes any employer if—

21 “(A) such employer met the requirements
22 under such section for any preceding calendar
23 year after 1998, and

24 “(B) such employer employed an average
25 of 250 or fewer employees on business days

during each preceding calendar year after
1998.”.

Subtitle D—Community Health Organizations

SEC. 231. PROMOTION OF PROVISION OF INSURANCE BY COMMUNITY HEALTH ORGANIZATIONS.

(a) WAIVER OF STATE LICENSURE REQUIREMENT
FOR COMMUNITY HEALTH ORGANIZATIONS IN CERTAIN
CASES.—Subpart I of part D of title III of the Public
Health Service Act is amended by adding at the end the
following new section:

“WAIVER OF STATE LICENSURE REQUIREMENT FOR
COMMUNITY HEALTH ORGANIZATIONS IN CERTAIN CASES

“SEC. 330B. (a) WAIVER AUTHORIZED.—

“(1) IN GENERAL.—A community health organization may offer health insurance coverage in a State notwithstanding that it is not licensed in such a State to offer such coverage if—

“(A) the organization files an application for waiver of the licensure requirement with the Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) by not later than November 1, 2003; and

“(B) the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for ap-

1 proval of the application described in subpara-
2 graph (A), (B), or (C) of paragraph (2) has
3 been met.

4 “(2) GROUNDS FOR APPROVAL OF WAIVER.—

5 “(A) FAILURE TO ACT ON LICENSURE AP-
6 PLICATION ON A TIMELY BASIS.—The ground
7 for approval of such a waiver application de-
8 scribed in this subparagraph is that the State
9 has failed to complete action on a licensing ap-
10 plication of the organization within 90 days of
11 the date of the State’s receipt of a substantially
12 complete application. No period before the date
13 of the enactment of this section shall be in-
14 cluded in determining such 90-day period.

15 “(B) DENIAL OF APPLICATION BASED ON
16 DISCRIMINATORY TREATMENT.—The ground for
17 approval of such a waiver application described
18 in this subparagraph is that the State has de-
19 nied such a licensing application and the stand-
20 ards or review process imposed by the State as
21 a condition of approval of the license or as the
22 basis for such denial by the State imposes any
23 material requirements, procedures, or standards
24 (other than solvency requirements) to such or-
25 ganizations that are not generally applicable to

1 other entities engaged in a substantially similar
2 business.

3 “(C) DENIAL OF APPLICATION BASED ON
4 APPLICATION OF SOLVENCY REQUIREMENTS.—

5 With respect to waiver applications filed on or
6 after the date of publication of solvency stand-
7 ards established by the Secretary under sub-
8 section (d), the ground for approval of such a
9 waiver application described in this subpara-
10 graph is that the State has denied such a li-
11 censing application based (in whole or in part)
12 on the organization’s failure to meet applicable
13 State solvency requirements and such require-
14 ments are not the same as the solvency stand-
15 ards established by the Secretary. For purposes
16 of this subparagraph, the term solvency require-
17 ments means requirements relating to solvency
18 and other matters covered under the standards
19 established by the Secretary under subsection
20 (d).

21 “(3) TREATMENT OF WAIVER.—In the case of
22 a waiver granted under this subsection for a commu-
23 nity health organization with respect to a State—

1 “(A) LIMITATION TO STATE.—The waiver
2 shall be effective only with respect to that State
3 and does not apply to any other State.

4 “(B) LIMITATION TO 36-MONTH PERIOD.—
5 The waiver shall be effective only for a 36-
6 month period but may be renewed for up to 36
7 additional months if the Secretary determines
8 that such an extension is appropriate.

9 “(C) CONDITIONED ON COMPLIANCE WITH
10 CONSUMER PROTECTION AND QUALITY STAND-
11 ARDS.—The continuation of the waiver is condi-
12 tioned upon the organization’s compliance with
13 the requirements described in paragraph (5).

14 “(D) PREEMPTION OF STATE LAW.—Any
15 provisions of law of that State which relate to
16 the licensing of the organization and which pro-
17 hibit the organization from providing health in-
18 surance coverage shall be superseded.

19 “(4) PROMPT ACTION ON APPLICATION.—The
20 Secretary shall grant or deny such a waiver applica-
21 tion within 60 days after the date the Secretary de-
22 termines that a substantially complete waiver appli-
23 cation has been filed. Nothing in this section shall
24 be construed as preventing an organization which

1 has had such a waiver application denied from sub-
2 mitting a subsequent waiver application.

3 “(5) APPLICATION AND ENFORCEMENT OF
4 STATE CONSUMER PROTECTION AND QUALITY
5 STANDARDS.—A waiver granted under this sub-
6 section to an organization with respect to licensing
7 under State law is conditioned upon the organiza-
8 tion’s compliance with all consumer protection and
9 quality standards insofar as such standards—

10 “(A) would apply in the State to the com-
11 munity health organization if it were licensed as
12 an entity offering health insurance coverage
13 under State law; and

14 “(B) are generally applicable to other risk-
15 bearing managed care organizations and plans
16 in the State.

17 “(6) REPORT.—By not later than December 31,
18 2002, the Secretary shall submit to the Committee
19 on Commerce of the House of Representatives and
20 the Committee on Labor and Human Resources of
21 the Senate a report regarding whether the waiver
22 process under this subsection should be continued
23 after December 31, 2003.

24 “(b) ASSUMPTION OF FULL FINANCIAL RISK.—To
25 qualify for a waiver under subsection (a), the community

1 health organization shall assume full financial risk on a
2 prospective basis for the provision of covered health care
3 services, except that the organization—

4 “(1) may obtain insurance or make other ar-
5 rangements for the cost of providing to any enrolled
6 member such services the aggregate value of which
7 exceeds such aggregate level as the Secretary speci-
8 fies from time to time;

9 “(2) may obtain insurance or make other ar-
10 rangements for the cost of such services provided to
11 its enrolled members other than through the organi-
12 zation because medical necessity required their pro-
13 vision before they could be secured through the orga-
14 nization;

15 “(3) may obtain insurance or make other ar-
16 rangements for not more than 90 percent of the
17 amount by which its costs for any of its fiscal years
18 exceed 105 percent of its income for such fiscal year;
19 and

20 “(4) may make arrangements with physicians
21 or other health care professionals, health care insti-
22 tutions, or any combination of such individuals or
23 institutions to assume all or part of the financial
24 risk on a prospective basis for the provision of

1 health services by the physicians or other health pro-
2 fessionals or through the institutions.

3 “(c) CERTIFICATION OF PROVISION AGAINST RISK
4 OF INSOLVENCY FOR UNLICENSED CHO’S.—

5 “(1) IN GENERAL.—Each community health or-
6 ganization that is not licensed by a State and for
7 which a waiver application has been approved under
8 subsection (a)(1), shall meet standards established
9 by the Secretary under subsection (d) relating to the
10 financial solvency and capital adequacy of the orga-
11 nization.

12 “(2) CERTIFICATION PROCESS FOR SOLVENCY
13 STANDARDS FOR CHO’S.—The Secretary shall estab-
14 lish a process for the receipt and approval of appli-
15 cations of a community health organization de-
16 scribed in paragraph (1) for certification (and peri-
17 odic recertification) of the organization as meeting
18 such solvency standards. Under such process, the
19 Secretary shall act upon such a certification applica-
20 tion not later than 60 days after the date the appli-
21 cation has been received.

22 “(d) ESTABLISHMENT OF SOLVENCY STANDARDS
23 FOR COMMUNITY HEALTH ORGANIZATIONS.—

24 “(1) IN GENERAL.—The Secretary shall estab-
25 lish, on an expedited basis and by rule pursuant to

1 section 553 of title 5, United States Code and
2 through the Health Resources and Services Adminis-
3 tration, standards described in subsection (c)(1) (re-
4 lating to financial solvency and capital adequacy)
5 that entities must meet to obtain a waiver under
6 subsection (a)(2)(C). In establishing such standards,
7 the Secretary shall consult with interested organiza-
8 tions, including the National Association of Insur-
9 ance Commissioners, the Academy of Actuaries, and
10 organizations representing Federally qualified health
11 centers.

12 “(2) FACTORS TO CONSIDER FOR SOLVENCY
13 STANDARDS.—In establishing solvency standards for
14 community health organizations under paragraph
15 (1), the Secretary shall take into account—

16 “(A) the delivery system assets of such an
17 organization and ability of such an organization
18 to provide services to enrollees;

19 “(B) alternative means of protecting
20 against insolvency, including reinsurance, unre-
21 stricted surplus, letters of credit, guarantees,
22 organizational insurance coverage, partnerships
23 with other licensed entities, and valuation at-
24 tributable to the ability of such an organization

1 to meet its service obligations through direct
2 delivery of care; and

3 “(C) any standards developed by the Na-
4 tional Association of Insurance Commissioners
5 specifically for risk-based health care delivery
6 organizations.

7 “(3) ENROLLEE PROTECTION AGAINST INSOL-
8 VENCY.—Such standards shall include provisions to
9 prevent enrollees from being held liable to any per-
10 son or entity for the organization’s debts in the
11 event of the organization’s insolvency.

12 “(4) DEADLINE.—Such standards shall be pro-
13 mulgated in a manner so they are first effective by
14 not later than April 1, 1999.

15 “(e) DEFINITIONS.—In this section:

16 “(1) COMMUNITY HEALTH ORGANIZATION.—
17 The term ‘community health organization’ means an
18 organization that is a Federally-qualified health cen-
19 ter or is controlled by one or more Federally-quali-
20 fied health centers.

21 “(2) FEDERALLY-QUALIFIED HEALTH CEN-
22 TER.—The term ‘Federally-qualified health center’
23 has the meaning given such term in section
24 1905(l)(2)(B) of the Social Security Act.

1 “(3) HEALTH INSURANCE COVERAGE.—The
2 term ‘health insurance coverage’ has the meaning
3 given such term in section 2791(b)(1).

4 “(4) CONTROL.—The term ‘control’ means the
5 possession, whether direct or indirect, of the power
6 to direct or cause the direction of the management
7 and policies of the organization through member-
8 ship, board representation, or an ownership interest
9 equal to or greater than 50.1 percent.”.

10 **TITLE III—AMENDMENTS TO** 11 **THE INTERNAL REVENUE** 12 **CODE OF 1986**

13 **Subtitle A—Patient Protections**

14 **SEC. 301. PATIENT ACCESS TO UNRESTRICTED MEDICAL** 15 **ADVICE, EMERGENCY MEDICAL CARE, OB-** 16 **STETRIC AND GYNECOLOGICAL CARE, PEDI-** 17 **ATRIC CARE, AND CONTINUITY OF CARE.**

18 Subchapter B of chapter 100 of the Internal Revenue
19 Code of 1986 is amended—

20 (1) in the table of sections, by inserting after
21 the item relating to section 9812 the following new
22 item:

“Sec. 9813. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.”; and

23 (2) by inserting after section 9812 the fol-
24 lowing:

1 **"SEC. 9813. PATIENT ACCESS TO UNRESTRICTED MEDICAL**
2 **ADVICE, EMERGENCY MEDICAL CARE, OB-**
3 **STETRIC AND GYNECOLOGICAL CARE, PEDI-**
4 **ATRIC CARE, AND CONTINUITY OF CARE.**

5 **"(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL**
6 **ADVICE.—**

7 **"(1) IN GENERAL.—**In the case of any health
8 care professional acting within the lawful scope of
9 practice in the course of carrying out a contractual
10 employment arrangement or other direct contractual
11 arrangement between such professional and a group
12 health plan, the plan with which such contractual
13 employment arrangement or other direct contractual
14 arrangement is maintained by the professional may
15 not impose on such professional under such arrange-
16 ment any prohibition or restriction with respect to
17 advice, provided to a participant or beneficiary
18 under the plan who is a patient, about the health
19 status of the participant or beneficiary or the med-
20 ical care or treatment for the condition or disease of
21 the participant or beneficiary, regardless of whether
22 benefits for such care or treatment are provided
23 under the plan.

24 **"(2) HEALTH CARE PROFESSIONAL DEFINED.—**
25 For purposes of this paragraph, the term 'health
26 care professional' means a physician (as defined in

1 section 1861(r) of the Social Security Act) or other
2 health care professional if coverage for the profes-
3 sional's services is provided under the group health
4 plan for the services of the professional. Such term
5 includes a podiatrist, optometrist, chiropractor, psy-
6 chologist, dentist, physician assistant, physical or oc-
7 cupational therapist and therapy assistant, speech-
8 language pathologist, audiologist, registered or li-
9 censed practical nurse (including nurse practitioner,
10 clinical nurse specialist, certified registered nurse
11 anesthetist, and certified nurse-midwife), licensed
12 certified social worker, registered respiratory thera-
13 pist, and certified respiratory therapy technician.

14 “(3) RULE OF CONSTRUCTION.—Nothing in
15 this subsection shall be construed to require the
16 sponsor of a group health plan to engage in any
17 practice that would violate its religious beliefs or
18 moral convictions.

19 “(b) PATIENT ACCESS TO EMERGENCY MEDICAL
20 CARE.—

21 “(1) COVERAGE OF EMERGENCY SERVICES.—

22 “(A) IN GENERAL.—If a group health plan
23 provides any benefits with respect to emergency
24 services (as defined in subparagraph (B)(ii)), or
25 ambulance services, the plan shall cover emer-

1 agency services (including emergency ambulance
2 services as defined in subparagraph (B)(iii))
3 furnished under the plan—

4 “(i) without the need for any prior
5 authorization determination;

6 “(ii) whether or not the health care
7 provider furnishing such services is a par-
8 ticipating provider with respect to such
9 services;

10 “(iii) in a manner so that, if such
11 services are provided to a participant or
12 beneficiary by a nonparticipating health
13 care provider, the participant or bene-
14 ficiary is not liable for amounts that ex-
15 ceed the amounts of liability that would be
16 incurred if the services were provided by a
17 participating provider; and

18 “(iv) without regard to any other term
19 or condition of such plan (other than ex-
20 clusion or coordination of benefits, or an
21 affiliation or waiting period, permitted
22 under section 701 and other than applica-
23 ble cost sharing).

24 “(B) DEFINITIONS.—In this subsection:

1 “(i) EMERGENCY MEDICAL CONDI-
2 TION.—The term ‘emergency medical con-
3 dition’ means—

4 “(I) a medical condition mani-
5 festing itself by acute symptoms of
6 sufficient severity (including severe
7 pain) such that a prudent layperson,
8 who possesses an average knowledge
9 of health and medicine, could reason-
10 ably expect the absence of immediate
11 medical attention to result in a condi-
12 tion described in clause (i), (ii), or
13 (iii) of section 1867(e)(1)(A) of the
14 Social Security Act (42 U.S.C.
15 1395dd(e)(1)(A)); and

16 “(II) a medical condition mani-
17 festing itself in a neonate by acute
18 symptoms of sufficient severity (in-
19 cluding severe pain) such that a pru-
20 dent health care professional could
21 reasonably expect the absence of im-
22 mediate medical attention to result in
23 a condition described in clause (i),
24 (ii), or (iii) of section 1867(e)(1)(A)
25 of the Social Security Act.

1 “(ii) EMERGENCY SERVICES.—The
2 term ‘emergency services’ means—

3 “(I) with respect to an emer-
4 gency medical condition described in
5 clause (i)(I), a medical screening ex-
6 amination (as required under section
7 1867 of the Social Security Act, 42
8 U.S.C. 1395dd)) that is within the ca-
9 pability of the emergency department
10 of a hospital, including ancillary serv-
11 ices routinely available to the emer-
12 gency department to evaluate an
13 emergency medical condition (as de-
14 fined in clause (i)) and also, within
15 the capabilities of the staff and facili-
16 ties at the hospital, such further med-
17 ical examination and treatment as are
18 required under section 1867 of such
19 Act to stabilize the patient; or

20 “(II) with respect to an emer-
21 gency medical condition described in
22 clause (i)(II), medical treatment for
23 such condition rendered by a health
24 care provider in a hospital to a
25 neonate, including available hospital

1 ancillary services in response to an ur-
2 gent request of a health care profes-
3 sional and to the extent necessary to
4 stabilize the neonate.

5 “(iii) EMERGENCY AMBULANCE SERV-
6 ICES.—The term ‘emergency ambulance
7 services’ means ambulance services (as de-
8 fined for purposes of section 1861(s)(7) of
9 the Social Security Act) furnished to trans-
10 port an individual who has an emergency
11 medical condition (as defined in clause (i))
12 to a hospital for the receipt of emergency
13 services (as defined in clause (ii)) in a case
14 in which appropriate emergency medical
15 screening examinations are covered under
16 the plan pursuant to paragraph (1)(A) and
17 a prudent layperson, with an average
18 knowledge of health and medicine, could
19 reasonably expect that the absence of such
20 transport would result in placing the
21 health of the individual in serious jeopardy,
22 serious impairment of bodily function, or
23 serious dysfunction of any bodily organ or
24 part.

1 “(iv) STABILIZE.—The term ‘to sta-
2 bilize’ means, with respect to an emergency
3 medical condition, to provide such medical
4 treatment of the condition as may be nec-
5 essary to assure, within reasonable medical
6 probability, that no material deterioration
7 of the condition is likely to result from or
8 occur during the transfer of the individual
9 from a facility.

10 “(v) NONPARTICIPATING.—The term
11 ‘nonparticipating’ means, with respect to a
12 health care provider that provides health
13 care items and services to a participant or
14 beneficiary under group health plan, a
15 health care provider that is not a partici-
16 pating health care provider with respect to
17 such items and services.

18 “(vi) PARTICIPATING.—The term
19 ‘participating’ means, with respect to a
20 health care provider that provides health
21 care items and services to a participant or
22 beneficiary under group health plan, a
23 health care provider that furnishes such
24 items and services under a contract or
25 other arrangement with the plan.

1 “(c) PATIENT RIGHT TO OBSTETRIC AND GYNECO-
2 LOGICAL CARE.—

3 “(1) IN GENERAL.—In any case in which a
4 group health plan—

5 “(A) provides benefits under the terms of
6 the plan consisting of—

7 “(i) gynecological care (such as pre-
8 ventive women’s health examinations); or

9 “(ii) obstetric care (such as preg-
10 nancy-related services),

11 provided by a participating health care profes-
12 sional who specializes in such care (or provides
13 benefits consisting of payment for such care);
14 and

15 “(B) requires or provides for designation
16 by a participant or beneficiary of a partici-
17 pating primary care provider,

18 if the primary care provider designated by such a
19 participant or beneficiary is not such a health care
20 professional, then the plan shall meet the require-
21 ments of paragraph (2).

22 “(2) REQUIREMENTS.—A group health plan
23 meets the requirements of this paragraph, in connec-
24 tion with benefits described in paragraph (1) con-
25 sisting of care described in clause (i) or (ii) of para-

graph (1)(A) (or consisting of payment therefor), if the plan—

“(A) does not require authorization or a referral by the primary care provider in order to obtain such benefits; and

“(B) treats the ordering of other care of the same type, by the participating health care professional providing the care described in clause (i) or (ii) of paragraph (1)(A), as the authorization of the primary care provider with respect to such care.

“(3) HEALTH CARE PROFESSIONAL DEFINED.—

For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse midwife or nurse practitioner) who is licensed, accredited, or certified under State law to provide obstetric and gynecological health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their

1 licensure to perform obstetric and gynecological
2 health care services. Nothing in paragraph (2)(B)
3 shall waive any requirements of coverage relating to
4 medical necessity or appropriateness with respect to
5 coverage of gynecological or obstetric care so or-
6 dered.

7 “(5) TREATMENT OF MULTIPLE COVERAGE OP-
8 TIONS.—In the case of a plan providing benefits
9 under two or more coverage options, the require-
10 ments of this subsection shall apply separately with
11 respect to each coverage option.

12 “(d) PATIENT RIGHT TO PEDIATRIC CARE.—

13 “(1) IN GENERAL.—In any case in which a
14 group health plan provides benefits consisting of
15 routine pediatric care provided by a participating
16 health care professional who specializes in pediatrics
17 (or consisting of payment for such care) and the
18 plan requires or provides for designation by a partic-
19 ipant or beneficiary of a participating primary care
20 provider, the plan shall provide that such a partici-
21 pating health care professional may be designated, if
22 available, by a parent or guardian of any beneficiary
23 under the plan is who under 18 years of age, as the
24 primary care provider with respect to any such bene-
25 fits.

1 “(2) HEALTH CARE PROFESSIONAL DEFINED.—

2 For purposes of this subsection, the term ‘health
3 care professional’ means an individual who is li-
4 censed, accredited, or certified under State law to
5 provide pediatric health care services and who is op-
6 erating within the scope of such licensure, accredita-
7 tion, or certification.

8 “(3) CONSTRUCTION.—Nothing in paragraph

9 (1) shall be construed as preventing a plan from of-
10 fering (but not requiring a participant or beneficiary
11 to accept) a health care professional trained,
12 credentialed, and operating within the scope of their
13 licensure to perform pediatric health care services.
14 Nothing in paragraph (1) shall waive any require-
15 ments of coverage relating to medical necessity or
16 appropriateness with respect to coverage of pediatric
17 care so ordered.

18 “(4) TREATMENT OF MULTIPLE COVERAGE OP-

19 TIONS.—In the case of a plan providing benefits
20 under two or more coverage options, the require-
21 ments of this subsection shall apply separately with
22 respect to each coverage option.

23 “(e) CONTINUITY OF CARE.—

24 “(1) IN GENERAL.—

“(A) TERMINATION OF PROVIDER.—If a contract between a group health plan and a health care provider is terminated (as defined in subparagraph (D)(ii)), or benefits provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who, at the time of such termination, is a participant or beneficiary in the plan and is scheduled to undergo surgery (including an organ transplantation), is undergoing treatment for pregnancy, or is determined to be terminally ill (as defined in section 1861(dd)(3)(A) of the Social Security Act) and is undergoing treatment for the terminal illness, the plan shall—

“(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this subsection; and

“(ii) subject to paragraph (3), permit the individual to elect to continue to be covered with respect to treatment by the provider for such surgery, pregnancy, or

1 illness during a transitional period (pro-
2 vided under paragraph (2)).

3 “(B) TREATMENT OF TERMINATION OF
4 CONTRACT WITH HEALTH INSURANCE
5 ISSUER.—If a contract for the provision of
6 health insurance coverage between a group
7 health plan and a health insurance issuer is ter-
8 minated and, as a result of such termination,
9 coverage of services of a health care provider is
10 terminated with respect to an individual, the
11 provisions of subparagraph (A) (and the suc-
12 ceeding provisions of this subsection) shall
13 apply under the plan in the same manner as if
14 there had been a contract between the plan and
15 the provider that had been terminated, but only
16 with respect to benefits that are covered under
17 the plan after the contract termination.

18 “(C) TERMINATION DEFINED.—For pur-
19 poses of this subsection, the term ‘terminated’
20 includes, with respect to a contract, the expira-
21 tion or nonrenewal of the contract, but does not
22 include a termination of the contract by the
23 plan for failure to meet applicable quality
24 standards or for fraud.

25 “(2) TRANSITIONAL PERIOD.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraphs (B) through (D), the transi-
3 tional period under this paragraph shall extend
4 up to 90 days (as determined by the treating
5 health care professional) after the date of the
6 notice described in paragraph (1)(A)(i) of the
7 provider’s termination.

8 “(B) SCHEDULED SURGERY.—If surgery
9 was scheduled for an individual before the date
10 of the announcement of the termination of the
11 provider status under paragraph (1)(A)(i), the
12 transitional period under this paragraph with
13 respect to the surgery or transplantation.

14 “(C) PREGNANCY.—If—

15 “(i) a participant or beneficiary was
16 determined to be pregnant at the time of
17 a provider’s termination of participation,
18 and

19 “(ii) the provider was treating the
20 pregnancy before date of the termination,
21 the transitional period under this paragraph
22 with respect to provider’s treatment of the
23 pregnancy shall extend through the provision of
24 post-partum care directly related to the deliv-
25 ery.

1 “(D) TERMINAL ILLNESS.—If—

2 “(i) a participant or beneficiary was
3 determined to be terminally ill (as deter-
4 mined under section 1861(dd)(3)(A) of the
5 Social Security Act) at the time of a pro-
6 vider’s termination of participation, and

7 “(ii) the provider was treating the ter-
8 minal illness before the date of termi-
9 nation,

10 the transitional period under this paragraph
11 shall extend for the remainder of the individ-
12 ual’s life for care directly related to the treat-
13 ment of the terminal illness or its medical
14 manifestations.

15 “(3) PERMISSIBLE TERMS AND CONDITIONS.—

16 A group health plan may condition coverage of con-
17 tinued treatment by a provider under paragraph
18 (1)(A)(i) upon the individual notifying the plan of
19 the election of continued coverage and upon the pro-
20 vider agreeing to the following terms and conditions:

21 “(A) The provider agrees to accept reim-
22 bursement from the plan and individual in-
23 volved (with respect to cost-sharing) at the
24 rates applicable prior to the start of the transi-
25 tional period as payment in full (or, in the case

1 described in paragraph (1)(B), at the rates ap-
2 plicable under the replacement plan after the
3 date of the termination of the contract with the
4 health insurance issuer) and not to impose cost-
5 sharing with respect to the individual in an
6 amount that would exceed the cost-sharing that
7 could have been imposed if the contract referred
8 to in paragraph (1)(A) had not been termi-
9 nated.

10 “(B) The provider agrees to adhere to the
11 quality assurance standards of the plan respon-
12 sible for payment under subparagraph (A) and
13 to provide to such plan necessary medical infor-
14 mation related to the care provided.

15 “(C) The provider agrees otherwise to ad-
16 here to such plan’s policies and procedures, in-
17 cluding procedures regarding referrals and ob-
18 taining prior authorization and providing serv-
19 ices pursuant to a treatment plan (if any) ap-
20 proved by the plan.

21 “(D) The provider agrees to provide tran-
22 sitional care to all participants and beneficiaries
23 who are eligible for and elect to have coverage
24 of such care from such provider.

1 “(E) If the provider initiates the termi-
2 nation, the provider has notified the plan within
3 30 days prior to the effective date of the termi-
4 nation of—

5 “(i) whether the provider agrees to
6 permissible terms and conditions (as set
7 forth in this paragraph) required by the
8 plan, and

9 “(ii) if the provider agrees to the
10 terms and conditions, the specific plan
11 beneficiaries and participants undergoing a
12 course of treatment from the provider who
13 the provider believes, at the time of the no-
14 tification, would be eligible for transitional
15 care under this subsection.

16 “(4) CONSTRUCTION.—Nothing in this sub-
17 section shall be construed to—

18 “(A) require the coverage of benefits which
19 would not have been covered if the provider in-
20 volved remained a participating provider, or

21 “(B) prohibit a group health plan from
22 conditioning a provider’s participation on the
23 provider’s agreement to provide transitional
24 care to all participants and beneficiaries eligible

1 to obtain coverage of such care furnished by the
2 provider as set forth under this subsection.

3 “(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
4 APPROVED CANCER CLINICAL TRIALS.—

5 “(1) COVERAGE.—

6 “(A) IN GENERAL.—If a group health plan
7 provides coverage to a qualified individual (as
8 defined in paragraph (2)), the plan—

9 “(i) may not deny the individual par-
10 ticipation in the clinical trial referred to in
11 paragraph (2)(B);

12 “(ii) subject to paragraphs (2), (3),
13 and (4), may not deny (or limit or impose
14 additional conditions on) the coverage of
15 routine patient costs for items and services
16 furnished in connection with participation
17 in the trial; and

18 “(iii) may not discriminate against the
19 individual on the basis of the participation
20 of the participant or beneficiary in such
21 trial.

22 “(B) EXCLUSION OF CERTAIN COSTS.—

23 For purposes of subparagraph (A)(ii), routine
24 patient costs do not include the cost of the tests

1 or measurements conducted primarily for the
2 purpose of the clinical trial involved.

3 “(C) USE OF IN-NETWORK PROVIDERS.—If
4 one or more participating providers is partici-
5 pating in a clinical trial, nothing in subpara-
6 graph (A) shall be construed as preventing a
7 plan from requiring that a qualified individual
8 participate in the trial through such a partici-
9 pating provider if the provider will accept the
10 individual as a participant in the trial.

11 “(2) QUALIFIED INDIVIDUAL DEFINED.—For
12 purposes of paragraph (1), the term ‘qualified indi-
13 vidual’ means an individual who is a participant or
14 beneficiary in a group health plan and who meets
15 the following conditions:

16 “(A)(i) The individual has been diagnosed
17 with cancer.

18 “(ii) The individual is eligible to partici-
19 pate in an approved clinical trial according to
20 the trial protocol with respect to treatment of
21 cancer.

22 “(iii) The individual’s participation in the
23 trial offers meaningful potential for significant
24 clinical benefit for the individual.

25 “(B) Either—

1 “(i) the referring physician is a par-
2 ticipating health care professional and has
3 concluded that the individual’s participa-
4 tion in such trial would be appropriate
5 based upon satisfaction by the individual of
6 the conditions described in subparagraph
7 (A); or

8 “(ii) the individual provides medical
9 and scientific information establishing that
10 the individual’s participation in such trial
11 would be appropriate based upon the satis-
12 faction by the individual of the conditions
13 described in subparagraph (A).

14 “(3) PAYMENT.—

15 “(A) IN GENERAL.—A group health plan
16 shall provide for payment for routine patient
17 costs described in paragraph (1)(B) but is not
18 required to pay for costs of items and services
19 that are reasonably expected to be paid for by
20 the sponsors of an approved clinical trial.

21 “(B) ROUTINE PATIENT CARE COSTS.—

22 “(i) IN GENERAL.—For purposes of
23 this paragraph, the term ‘routine patient
24 care costs’ shall include the costs associ-

1 ated with the provision of items and serv-
2 ices that—

3 “(I) would otherwise be covered
4 under the group health plan if such
5 items and services were not provided
6 in connection with an approved clin-
7 ical trial program; and

8 “(II) are furnished according to
9 the protocol of an approved clinical
10 trial program.

11 “(ii) EXCLUSION.—For purposes of
12 this paragraph, ‘routine patient care costs’
13 shall not include the costs associated with
14 the provision of—

15 (I) an investigational drug or de-
16 vice, unless the Secretary has author-
17 ized the manufacturer of such drug or
18 device to charge for such drug or de-
19 vice; or

20 (II) any item or service supplied
21 without charge by the sponsor of the
22 approved clinical trial program.

23 “(C) PAYMENT RATE.—For purposes of
24 this subsection—

1 “(i) PARTICIPATING PROVIDERS.—In
2 the case of covered items and services pro-
3 vided by a participating provider, the pay-
4 ment rate shall be at the agreed upon rate.

5 “(ii) NONPARTICIPATING PRO-
6 VIDERS.—In the case of covered items and
7 services provided by a nonparticipating
8 provider, the payment rate shall be at the
9 rate the plan would normally pay for com-
10 parable items or services under clause (i).

11 “(4) APPROVED CLINICAL TRIAL DEFINED.—

12 “(A) IN GENERAL.—For purposes of this
13 subsection, the term ‘approved clinical trial’
14 means a cancer clinical research study or can-
15 cer clinical investigation approved by an Institu-
16 tional Review Board.

17 “(B) CONDITIONS FOR DEPARTMENTS.—
18 The conditions described in this paragraph, for
19 a study or investigation conducted by a Depart-
20 ment, are that the study or investigation has
21 been reviewed and approved through a system
22 of peer review that the Secretary determines—

23 “(i) to be comparable to the system of
24 peer review of studies and investigations

1 used by the National Institutes of Health,
2 and

3 “(ii) assures unbiased review of the
4 highest scientific standards by qualified in-
5 dividuals who have no interest in the out-
6 come of the review.

7 “(5) CONSTRUCTION.—Nothing in this sub-
8 section shall be construed to limit a plan’s coverage
9 with respect to clinical trials.

10 “(6) PLAN SATISFACTION OF CERTAIN RE-
11 QUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

12 “(A) IN GENERAL.—For purposes of this
13 subsection, insofar as a group health plan pro-
14 vides benefits in the form of health insurance
15 coverage through a health insurance issuer, the
16 plan shall be treated as meeting the require-
17 ments of this subsection with respect to such
18 benefits and not be considered as failing to
19 meet such requirements because of a failure of
20 the issuer to meet such requirements so long as
21 the plan sponsor or its representatives did not
22 cause such failure by the issuer.

23 “(B) CONSTRUCTION.—Nothing in this
24 subsection shall be construed to affect or mod-
25 ify the responsibilities of the fiduciaries of a

1 group health plan under part 4 of subtitle B of
2 title I of the Employee Retirement Income Se-
3 curity Act of 1974.

4 “(7) STUDY AND REPORT.—

5 “(A) STUDY.—The Secretary shall analyze
6 cancer clinical research and its cost implications
7 for managed care, including differentiation in—

8 “(i) the cost of patient care in trials
9 versus standard care;

10 “(ii) the cost effectiveness achieved in
11 different sites of service;

12 “(iii) research outcomes;

13 “(iv) volume of research subjects
14 available in different sites of service;

15 “(v) access to research sites and clin-
16 ical trials by cancer patients;

17 “(vi) patient cost sharing or copay-
18 ment costs realized in different sites of
19 service;

20 “(vii) health outcomes experienced in
21 different sites of service;

22 “(viii) long term health care services
23 and costs experienced in different sites of
24 service;

“(ix) morbidity and mortality experienced in different sites of service; and

“(x) patient satisfaction and preference of sites of service.

“(B) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

“(i) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

“(ii) a projection of expenditures to such plans resulting from this section;

“(iii) an assessment of any impact on premiums resulting from this section; and

“(iv) recommendations regarding action on other diseases.”.

SEC. 302. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act, except that the Secretary of the Treasury may issue regulations before such date under such amendments. The Secretary shall first issue regulations necessary to carry out the amend-

1 ments made by this subtitle before the effective date there-
2 of.

3 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
4 enforcement action shall be taken, pursuant to the amend-
5 ments made by this subtitle, against a group health plan
6 with respect to a violation of a requirement imposed by
7 such amendments before the date of issuance of regula-
8 tions issued in connection with such requirement, if the
9 plan has sought to comply in good faith with such require-
10 ment.

11 (c) SPECIAL RULE FOR COLLECTIVE BARGAINING
12 AGREEMENTS.—In the case of a group health plan main-
13 tained pursuant to one or more collective bargaining
14 agreements between employee representatives and one or
15 more employers ratified before the date of the enactment
16 of this Act, the amendments made by this subtitle shall
17 not apply with respect to plan years beginning before the
18 later of—

19 (1) the date on which the last of the collective
20 bargaining agreements relating to the plan termi-
21 nates (determined without regard to any extension
22 thereof agreed to after the date of the enactment of
23 this Act); or

24 (2) January 1, 2002.

1 For purposes of this subsection, any plan amendment
2 made pursuant to a collective bargaining agreement relat-
3 ing to the plan which amends the plan solely to conform
4 to any requirement added by this subtitle shall not be
5 treated as a termination of such collective bargaining
6 agreement.

7 **Subtitle B—Medical Savings** 8 **Accounts**

9 **SEC. 311. EXPANSION OF AVAILABILITY OF MEDICAL SAV-** 10 **INGS ACCOUNTS.**

11 (a) REPEAL OF LIMITATIONS ON NUMBER OF MED- 12 ICAL SAVINGS ACCOUNTS.—

13 (1) IN GENERAL.—Subsections (i) and (j) of
14 section 220 of the Internal Revenue Code of 1986
15 are hereby repealed.

16 (2) CONFORMING AMENDMENT.—Paragraph (1)
17 of section 220(c) of such Code is amended by strik-
18 ing subparagraph (D).

19 (b) ALL EMPLOYERS MAY OFFER MEDICAL SAVINGS 20 ACCOUNTS.—

21 (1) IN GENERAL.—Subclause (I) of section
22 220(c)(1)(A)(iii) of such Code (defining eligible indi-
23 vidual) is amended by striking “and such employer
24 is a small employer”.

25 (2) CONFORMING AMENDMENTS.—

1 (A) Paragraph (1) of section 220(c) of
2 such Code is amended by striking subparagraph
3 (C).

4 (B) Subsection (c) of section 220 of such
5 Code is amended by striking paragraph (4) and
6 by redesignating paragraph (5) as paragraph
7 (4).

8 (c) INCREASE IN AMOUNT OF DEDUCTION ALLOWED
9 FOR CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

10 (1) IN GENERAL.—Paragraph (2) of section
11 220(b) of such Code is amended to read as follows:

12 “(2) MONTHLY LIMITATION.—The monthly lim-
13 itation for any month is the amount equal to $\frac{1}{12}$ of
14 the annual deductible (as of the first day of such
15 month) of the individual’s coverage under the high
16 deductible health plan.”.

17 (2) CONFORMING AMENDMENT.—Clause (ii) of
18 section 220(d)(1)(A) of such Code is amended by
19 striking “75 percent of”.

20 (d) BOTH EMPLOYERS AND EMPLOYEES MAY CON-
21 TRIBUTE TO MEDICAL SAVINGS ACCOUNTS.—Paragraph
22 (5) of section 220(b) of such Code is amended to read
23 as follows:

24 “(5) COORDINATION WITH EXCLUSION FOR EM-
25 PLOYER CONTRIBUTIONS.—The limitation which

would (but for this paragraph) apply under this subsection to the taxpayer for any taxable year shall be reduced (but not below zero) by the amount which would (but for section 106(b)) be includible in the taxpayer's gross income for such taxable year."

(e) REDUCTION OF PERMITTED DEDUCTIBLES
UNDER HIGH DEDUCTIBLE HEALTH PLANS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of such Code (defining high deductible health plan) is amended—

(A) by striking "\$1,500" in clause (i) and inserting "\$1,000", and

(B) by striking "\$3,000" in clause (ii) and inserting "\$2,000".

(2) CONFORMING AMENDMENT.—Subsection (g) of section 220 of such Code is amended to read as follows:

"(g) COST-OF-LIVING ADJUSTMENT.—

"(1) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 1998, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

"(A) such dollar amount, multiplied by

"(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar

1 year in which such taxable year begins by sub-
2 stituting ‘calendar year 1997’ for ‘calendar year
3 1992’ in subparagraph (B) thereof.

4 “(2) SPECIAL RULES.—In the case of the
5 \$1,000 amount in subsection (c)(2)(A)(i) and the
6 \$2,000 amount in subsection (c)(2)(A)(ii), para-
7 graph (1)(B) shall be applied by substituting ‘cal-
8 endar year 1999’ for ‘calendar year 1997’.

9 “(3) ROUNDING.—If any increase under para-
10 graph (1) or (2) is not a multiple of \$50, such in-
11 crease shall be rounded to the nearest multiple of
12 \$50.”.

13 (f) MEDICAL SAVINGS ACCOUNTS MAY BE OFFERED
14 UNDER CAFETERIA PLANS.—Subsection (f) of section
15 125 of such Code is amended by striking “106(b),”.

16 **SEC. 312. EFFECTIVE DATE.**

17 The amendments made by this subtitle shall apply to
18 taxable years beginning after December 31, 2000.

Subtitle C—Tax Incentives for Health Care

SEC. 321. DEDUCTION FOR HEALTH AND LONG-TERM CARE INSURANCE COSTS OF INDIVIDUALS NOT PARTICIPATING IN EMPLOYER-SUBSIDIZED HEALTH PLANS.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by redesignating section 222 as section 223 and by inserting after section 221 the following new section:

“SEC. 222. HEALTH AND LONG-TERM CARE INSURANCE COSTS.

“(a) IN GENERAL.—In the case of an individual, there shall be allowed as a deduction an amount equal to the applicable percentage of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer and the taxpayer’s spouse and dependents.

“(b) APPLICABLE PERCENTAGE.—For purposes of subsection (a), the applicable percentage shall be determined in accordance with the following table:

For taxable years beginning in calendar year—	The applicable percentage is—
2002, 2003, and 2004	25
2005	35
2006	65
2007 and thereafter	100.

“(c) LIMITATION BASED ON OTHER COVERAGE.—

1 “(1) COVERAGE UNDER CERTAIN SUBSIDIZED
2 EMPLOYER PLANS.—

3 “(A) IN GENERAL.—Subsection (a) shall
4 not apply to any taxpayer for any calendar
5 month for which the taxpayer participates in
6 any health plan maintained by any employer of
7 the taxpayer or of the spouse of the taxpayer if
8 50 percent or more of the cost of coverage
9 under such plan (determined under section
10 4980B and without regard to payments made
11 with respect to any coverage described in sub-
12 section (e)) is paid or incurred by the employer.

13 “(B) EMPLOYER CONTRIBUTIONS TO CAF-
14 ETERIA PLANS, FLEXIBLE SPENDING ARRANGE-
15 MENTS, AND MEDICAL SAVINGS ACCOUNTS.—
16 Employer contributions to a cafeteria plan, a
17 flexible spending or similar arrangement, or a
18 medical savings account which are excluded
19 from gross income under section 106 shall be
20 treated for purposes of subparagraph (A) as
21 paid by the employer.

22 “(C) AGGREGATION OF PLANS OF EM-
23 PLOYER.—A health plan which is not otherwise
24 described in subparagraph (A) shall be treated
25 as described in such subparagraph if such plan

would be so described if all health plans of persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 were treated as one health plan.

“(D) SEPARATE APPLICATION TO HEALTH INSURANCE AND LONG-TERM CARE INSURANCE.—Subparagraphs (A) and (C) shall be applied separately with respect to—

“(i) plans which include primarily coverage for qualified long-term care services or are qualified long-term care insurance contracts, and

“(ii) plans which do not include such coverage and are not such contracts.

“(2) COVERAGE UNDER CERTAIN FEDERAL PROGRAMS.—

“(A) IN GENERAL.—Subsection (a) shall not apply to any amount paid for any coverage for an individual for any calendar month if, as of the first day of such month, the individual is covered under any medical care program described in—

“(i) title XVIII, XIX, or XXI of the Social Security Act,

1 “(ii) chapter 55 of title 10, United
2 States Code,

3 “(iii) chapter 17 of title 38, United
4 States Code,

5 “(iv) chapter 89 of title 5, United
6 States Code, or

7 “(v) the Indian Health Care Improve-
8 ment Act.

9 “(B) EXCEPTIONS.—

10 “(i) QUALIFIED LONG-TERM CARE.—
11 Subparagraph (A) shall not apply to
12 amounts paid for coverage under a quali-
13 fied long-term care insurance contract.

14 “(ii) CONTINUATION COVERAGE OF
15 FEHBP.—Subparagraph (A)(iv) shall not
16 apply to coverage which is comparable to
17 continuation coverage under section
18 4980B.

19 “(d) LONG-TERM CARE DEDUCTION LIMITED TO
20 QUALIFIED LONG-TERM CARE INSURANCE CON-
21 TRACTS.—In the case of a qualified long-term care insur-
22 ance contract, only eligible long-term care premiums (as
23 defined in section 213(d)(10)) may be taken into account
24 under subsection (a).

1 “(e) DEDUCTION NOT AVAILABLE FOR PAYMENT OF
2 ANCILLARY COVERAGE PREMIUMS.—Any amount paid as
3 a premium for insurance which provides for—

4 “(1) coverage for accidents, disability, dental
5 care, vision care, or a specified illness, or

6 “(2) making payments of a fixed amount per
7 day (or other period) by reason of being hospitalized.
8 shall not be taken into account under subsection (a).

9 “(f) SPECIAL RULES.—

10 “(1) COORDINATION WITH DEDUCTION FOR
11 HEALTH INSURANCE COSTS OF SELF-EMPLOYED IN-
12 DIVIDUALS.—The amount taken into account by the
13 taxpayer in computing the deduction under section
14 162(l) shall not be taken into account under this
15 section.

16 “(2) COORDINATION WITH MEDICAL EXPENSE
17 DEDUCTION.—The amount taken into account by
18 the taxpayer in computing the deduction under this
19 section shall not be taken into account under section
20 213.

21 “(g) REGULATIONS.—The Secretary shall prescribe
22 such regulations as may be appropriate to carry out this
23 section, including regulations requiring employers to re-
24 port to their employees and the Secretary such informa-
25 tion as the Secretary determines to be appropriate.”.

1 (b) DEDUCTION ALLOWED WHETHER OR NOT TAX-
 2 PAYER ITEMIZES OTHER DEDUCTIONS.—Subsection (a)
 3 of section 62 of such Code is amended by inserting after
 4 paragraph (17) the following new item:

5 “(18) HEALTH AND LONG-TERM CARE INSUR-
 6 ANCE COSTS.—The deduction allowed by section
 7 222.”.

8 (c) CLERICAL AMENDMENT.—The table of sections
 9 for part VII of subchapter B of chapter 1 of such Code
 10 is amended by striking the last item and inserting the fol-
 11 lowing new items:

“Sec. 222. Health and long-term care insurance costs.

“Sec. 223. Cross reference.”.

12 (d) EFFECTIVE DATE.—The amendments made by
 13 this section shall apply to taxable years beginning after
 14 December 31, 2000.

15 **SEC. 322. REFUNDABLE CREDIT FOR HEALTH INSURANCE**
 16 **COVERAGE.**

17 (a) IN GENERAL.—Subpart C of part IV of sub-
 18 chapter A of chapter 1 of the Internal Revenue Code of
 19 1986 (relating to refundable credits) is amended by redes-
 20 ignating section 35 as section 36 and by inserting after
 21 section 34 the following new section:

22 **“SEC. 35. HEALTH INSURANCE COSTS.**

23 “(a) IN GENERAL.—In the case of an individual,
 24 there shall be allowed as a credit against the tax imposed

1 by this subtitle an amount equal to the amount paid dur-
2 ing the taxable year for qualified health insurance for the
3 taxpayer, his spouse, and dependents.

4 “(b) LIMITATIONS.—

5 “(1) IN GENERAL.—The amount allowed as a
6 credit under subsection (a) to the taxpayer for the
7 taxable year shall not exceed the sum of the monthly
8 limitations for coverage months during such taxable
9 year for each individual referred to in subsection (a)
10 for whom the taxpayer paid during the taxable year
11 any amount for coverage under qualified health in-
12 surance.

13 “(2) MONTHLY LIMITATION.—

14 “(A) IN GENERAL.—The monthly limita-
15 tion for an individual for each coverage month
16 of such individual during the taxable year is the
17 amount equal to 1/12 of—

18 “(i) \$1,000 if such individual is the
19 taxpayer,

20 “(ii) \$1,000 if—

21 “(I) such individual is the spouse
22 of the taxpayer,

23 “(II) the taxpayer and such
24 spouse are married as of the first day
25 of such month, and

1 “(III) the taxpayer files a joint
2 return for the taxable year, and

3 “(iii) \$500 if such individual is an in-
4 dividual for whom a deduction under sec-
5 tion 151(c) is allowable to the taxpayer for
6 such taxable year.

7 “(B) LIMITATION TO 2 DEPENDENTS.—
8 Not more than 2 individuals may be taken into
9 account by the taxpayer under subparagraph
10 (A)(iii).

11 “(C) SPECIAL RULE FOR MARRIED INDI-
12 VIDUALS.—In the case of an individual—

13 “(i) who is married (within the mean-
14 ing of section 7703) as of the close of the
15 taxable year but does not file a joint return
16 for such year, and

17 “(ii) who does not live apart from
18 such individual’s spouse at all times during
19 the taxable year,

20 the limitation imposed by subparagraph (B)
21 shall be divided equally between the individual
22 and the individual’s spouse unless they agree on
23 a different division.

24 “(3) COVERAGE MONTH.—For purposes of this
25 subsection—

1 “(A) IN GENERAL.—The term ‘coverage
2 month’ means, with respect to an individual,
3 any month if—

4 “(i) as of the first day of such month
5 such individual is covered by qualified
6 health insurance, and

7 “(ii) the premium for coverage under
8 such insurance for such month is paid by
9 the taxpayer.

10 “(B) EMPLOYER-SUBSIDIZED COV-
11 ERAGE.—Such term shall not include any
12 month for which such individual participates in
13 any subsidized health plan (within the meaning
14 of section 162(l)(2)) maintained by any em-
15 ployer of the taxpayer or of the spouse of the
16 taxpayer.

17 “(C) CAFETERIA PLAN AND FLEXIBLE
18 SPENDING ACCOUNT BENEFICIARIES.—Such
19 term shall not include any month during a tax-
20 able year if any amount is not includible in the
21 gross income of the taxpayer for such year
22 under section 106 with respect to—

23 “(i) a benefit chosen under a cafeteria
24 plan (as defined in section 125(d)), or

1 “(ii) a benefit provided under a flexi-
2 ble spending or similar arrangement.

3 “(D) MEDICARE AND MEDICAID.—Such
4 term shall not include any month with respect
5 to an individual if, as of the first day of such
6 month, such individual—

7 “(i) is entitled to any benefits under
8 title XVIII of the Social Security Act, or

9 “(ii) is a participant in the program
10 under title XIX of such Act.

11 “(E) CERTAIN OTHER COVERAGE.—Such
12 term shall not include any month during a tax-
13 able year with respect to an individual if, at any
14 time during such year, any benefit is provided
15 to such individual under—

16 “(i) chapter 17 of title 38, United
17 States Code, or

18 “(ii) any medical care program under
19 the Indian Health Care Improvement Act.

20 “(F) PRISONERS.—Such term shall not in-
21 clude any month with respect to an individual
22 if, as of the first day of such month, such indi-
23 vidual is imprisoned under Federal, State, or
24 local authority.

1 “(G) INSUFFICIENT PRESENCE IN UNITED
2 STATES.—Such term shall not include any
3 month during a taxable year with respect to an
4 individual if such individual is present in the
5 United States on fewer than 183 days during
6 such year (determined in accordance with sec-
7 tion 7701(b)(7)).

8 “(4) COORDINATION WITH DEDUCTION FOR
9 HEALTH INSURANCE COSTS OF SELF-EMPLOYED IN-
10 DIVIDUALS.—In the case of a taxpayer who is eligi-
11 ble to deduct any amount under section 162(l) for
12 the taxable year, this section shall apply only if the
13 taxpayer elects not to claim any amount as a deduc-
14 tion under such section for such year.

15 “(c) QUALIFIED HEALTH INSURANCE.—For pur-
16 poses of this section—

17 “(1) IN GENERAL.—The term ‘qualified health
18 insurance’ means insurance which constitutes med-
19 ical care as defined in section 213(d) without regard
20 to—

21 “(A) paragraph (1)(C) thereof, and

22 “(B) so much of paragraph (1)(D) thereof
23 as relates to qualified long-term care insurance
24 contracts.

1 “(2) EXCLUSION OF CERTAIN OTHER CON-
2 TRACTS.—Such term shall not include insurance if a
3 substantial portion of its benefits are excepted bene-
4 fits (as defined in section 9832(c)).

5 “(d) MEDICAL SAVINGS ACCOUNT CONTRIBU-
6 TIONS.—

7 “(1) IN GENERAL.—If a deduction would (but
8 for paragraph (2)) be allowed under section 220 to
9 the taxpayer for a payment for the taxable year to
10 the medical savings account of an individual, sub-
11 section (a) shall be applied by treating such payment
12 as a payment for qualified health insurance for such
13 individual.

14 “(2) DENIAL OF DOUBLE BENEFIT.—No deduc-
15 tion shall be allowed under section 220 for that por-
16 tion of the payments otherwise allowable as a deduc-
17 tion under section 220 for the taxable year which is
18 equal to the amount of credit allowed for such tax-
19 able year by reason of this subsection.

20 “(e) SPECIAL RULES.—

21 “(1) COORDINATION WITH MEDICAL EXPENSE
22 DEDUCTION.—The amount which would (but for this
23 paragraph) be taken into account by the taxpayer
24 under section 213 for the taxable year shall be re-

duced by the credit (if any) allowed by this section to the taxpayer for such year.

“(2) DENIAL OF CREDIT TO DEPENDENTS.—No credit shall be allowed under this section to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual’s taxable year begins.

“(3) INFLATION ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 2000, each dollar amount contained in subsection (b)(2)(A) shall be increased by an amount equal to—

“(A) such dollar amount, multiplied by

“(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting ‘calendar year 1999’ for ‘calendar year 1992’ in subparagraph (B) thereof.

Any increase determined under the preceding sentence shall be rounded to the nearest multiple of \$50 (\$25 in the case of the dollar amount in subsection (b)(2)(A)(iii)).”.

(b) INFORMATION REPORTING.—

1 (1) IN GENERAL.—Subpart B of part III of
2 subchapter A of chapter 61 of such Code (relating
3 to information concerning transactions with other
4 persons) is amended by inserting after section
5 6050S the following new section:

6 **“SEC. 6050T. RETURNS RELATING TO PAYMENTS FOR**
7 **QUALIFIED HEALTH INSURANCE.**

8 “(a) IN GENERAL.—Any person who, in connection
9 with a trade or business conducted by such person, re-
10 ceives payments during any calendar year from any indi-
11 vidual for coverage of such individual or any other indi-
12 vidual under creditable health insurance, shall make the
13 return described in subsection (b) (at such time as the
14 Secretary may by regulations prescribe) with respect to
15 each individual from whom such payments were received.

16 “(b) FORM AND MANNER OF RETURNS.—A return
17 is described in this subsection if such return—

18 “(1) is in such form as the Secretary may pre-
19 scribe, and

20 “(2) contains—

21 “(A) the name, address, and TIN of the
22 individual from whom payments described in
23 subsection (a) were received,

24 “(B) the name, address, and TIN of each
25 individual who was provided by such person

1 with coverage under creditable health insurance
2 by reason of such payments and the period of
3 such coverage, and

4 “(C) such other information as the Sec-
5 retary may reasonably prescribe.

6 “(c) CREDITABLE HEALTH INSURANCE.—For pur-
7 poses of this section, the term ‘creditable health insurance’
8 means qualified health insurance (as defined in section
9 35(c)) other than—

10 “(1) insurance under a subsidized group health
11 plan maintained by an employer, or

12 “(2) to the extent provided in regulations pre-
13 scribed by the Secretary, any other insurance cov-
14 ering an individual if no credit is allowable under
15 section 35 with respect to such coverage.

16 “(d) STATEMENTS TO BE FURNISHED TO INDIVID-
17 UALS WITH RESPECT TO WHOM INFORMATION IS RE-
18 QUIRED.—Every person required to make a return under
19 subsection (a) shall furnish to each individual whose name
20 is required under subsection (b)(2)(A) to be set forth in
21 such return a written statement showing—

22 “(1) the name and address of the person re-
23 quired to make such return and the phone number
24 of the information contact for such person,

1 “(2) the aggregate amount of payments de-
 2 scribed in subsection (a) received by the person re-
 3 quired to make such return from the individual to
 4 whom the statement is required to be furnished, and

5 “(3) the information required under subsection
 6 (b)(2)(B) with respect to such payments.

7 The written statement required under the preceding sen-
 8 tence shall be furnished on or before January 31 of the
 9 year following the calendar year for which the return
 10 under subsection (a) is required to be made.

11 “(e) RETURNS WHICH WOULD BE REQUIRED TO BE
 12 MADE BY 2 OR MORE PERSONS.—Except to the extent
 13 provided in regulations prescribed by the Secretary, in the
 14 case of any amount received by any person on behalf of
 15 another person, only the person first receiving such
 16 amount shall be required to make the return under sub-
 17 section (a).”.

18 (2) ASSESSABLE PENALTIES.—

19 (A) Subparagraph (B) of section
 20 6724(d)(1) of such Code (relating to defini-
 21 tions) is amended by redesignating clauses (xi)
 22 through (xvii) as clauses (xii) through (xviii),
 23 respectively, and by inserting after clause (x)
 24 the following new clause:

1 “(xi) section 6050T (relating to re-
2 turns relating to payments for qualified
3 health insurance),”.

4 (B) Paragraph (2) of section 6724(d) of
5 such Code is amended by striking “or” at the
6 end of the next to last subparagraph, by strik-
7 ing the period at the end of the last subpara-
8 graph and inserting “, or”, and by adding at
9 the end the following new subparagraph:

10 “(BB) section 6050T(d) (relating to re-
11 turns relating to payments for qualified health
12 insurance).”.

13 (3) CLERICAL AMENDMENT.—The table of sec-
14 tions for subpart B of part III of subchapter A of
15 chapter 61 of such Code is amended by inserting
16 after the item relating to section 6050S the fol-
17 lowing new item:

 “Sec. 6050T. Returns relating to payments for qualified health
 insurance.”.

18 (c) ADVANCE PAYMENT OF CREDIT FOR PUR-
19 CHASERS OF QUALIFIED HEALTH INSURANCE.—Chapter
20 77 of the Internal Revenue Code of 1986 (relating to mis-
21 cellaneous provisions) is amended by adding at the end
22 the following new section:

1 **"SEC. 7527. ADVANCE PAYMENT OF HEALTH INSURANCE**
2 **CREDIT FOR PURCHASERS OF QUALIFIED**
3 **HEALTH INSURANCE.**

4 “(a) GENERAL RULE.—In the case of an eligible indi-
5 vidual, the Secretary shall make payments to the provider
6 of such individual’s qualified health insurance equal to
7 such individual’s qualified health insurance credit advance
8 amount with respect to such provider.

9 “(b) ELIGIBLE INDIVIDUAL.—For purposes of this
10 section, the term ‘eligible individual’ means any
11 individual—

12 “(1) who purchases qualified health insurance
13 (as defined in section 35(c)), and

14 “(2) for whom a qualified health insurance
15 credit eligibility certificate is in effect.

16 “(c) QUALIFIED HEALTH INSURANCE CREDIT ELIGI-
17 BILITY CERTIFICATE.—For purposes of this section, a
18 qualified health insurance credit eligibility certificate is a
19 statement furnished by an individual to the Secretary
20 which—

21 “(1) certifies that the individual will be eligible
22 to receive the credit provided by section 35 for the
23 taxable year,

24 “(2) estimates the amount of such credit for
25 such taxable year, and

1 “(3) provides such other information as the
2 Secretary may require for purposes of this section.

3 “(d) QUALIFIED HEALTH INSURANCE CREDIT AD-
4 VANCE AMOUNT.—For purposes of this section, the term
5 ‘qualified health insurance credit advance amount’ means,
6 with respect to any provider of qualified health insurance,
7 the Secretary’s estimate of the amount of credit allowable
8 under section 35 to the individual for the taxable year
9 which is attributable to the insurance provided to the indi-
10 vidual by such provider.

11 “(e) REGULATIONS.—The Secretary shall prescribe
12 such regulations as may be necessary to carry out the pur-
13 poses of this section.”.

14 (c) CONFORMING AMENDMENTS.—

15 (1) Paragraph (2) of section 1324(b) of title
16 31, United States Code, is amended by inserting be-
17 fore the period “, or from section 35 of such Code”.

18 (2) The table of sections for subpart C of part
19 IV of subchapter A of chapter 1 of such Code is
20 amended by striking the last item and inserting the
21 following new items:

 “Sec. 35. Health insurance costs.

 “Sec. 36. Overpayments of tax.”.

22 (3) The table of sections for chapter 77 of such
23 Code is amended by adding at the end the following
24 new item:

“Sec. 7527. Advance payment of health insurance credit for purchasers of qualified health insurance.”.

1 (d) EFFECTIVE DATES.—

2 (1) IN GENERAL.—Except as provided by para-
3 graph (2), the amendments made by this section
4 shall apply to taxable years beginning after Decem-
5 ber 31, 1999.

6 (2) ADVANCE PAYMENT OF CREDIT FOR PUR-
7 CHASERS OF QUALIFIED HEALTH INSURANCE.—The
8 amendments made by subsections (c) and (d)(3)
9 shall take effect on January 1, 2000.

10 **SEC. 323. STUDY OF STATE SAFETY-NET HEALTH INSUR-**
11 **ANCE PROGRAMS FOR THE MEDICALLY UNIN-**
12 **SURABLE.**

13 (a) STUDY.—

14 (1) IN GENERAL.—The Secretary of Health and
15 Human Services shall provide for a study on the
16 current state of all existing State safety-net health
17 insurance programs (as defined in subsection (c)).
18 The study shall determine which forms of such pro-
19 grams are the most successful in making health in-
20 surance available to all willing payers regardless of
21 their health status.

22 (2) CONSULTATION.—In conducting the study
23 the Secretary shall consult with representatives of
24 the National Governors Association, the National

1 Association of Insurance Commissioners, national
2 associations representing health insurers, insurance
3 companies that administer and participate in State
4 safety-net health insurance programs, and individ-
5 uals who receive their health insurance through such
6 programs.

7 (b) REPORT.—The Secretary shall submit to Con-
8 gress, by not later than October 1, 2000, a detailed report
9 on the study conducted under subsection (a). The report
10 shall include recommendations on how Congress can best
11 strengthen State safety-net health insurance programs
12 where they currently exist and can encourage their estab-
13 lishment in States where they do not exist.

14 (c) STATE SAFETY-NET HEALTH INSURANCE PRO-
15 GRAM DEFINED.—For purposes of this section, the term
16 “State safety-net health insurance program” means a high
17 risk pool or similar arrangement provided under State law
18 for providing access of medically uninsurable individuals
19 to health insurance coverage. Such term may include such
20 other arrangements as the Secretary finds appropriate for
21 assuring the provision of health insurance coverage to
22 such individuals.

1 SEC. 324. CARRYOVER OF UNUSED BENEFITS FROM
2 CAFETERIA PLANS AND FLEXIBLE SPENDING
3 ARRANGEMENTS.

4 (a) IN GENERAL.—Section 125 of the Internal Rev-
5 enue Code of 1986 (relating to cafeteria plans) is amended
6 by redesignating subsections (h) and (i) as subsections (i)
7 and (j), respectively, and by inserting after subsection (g)
8 the following new subsection:

9 “(h) ALLOWANCE OF CARRYOVERS OF UNUSED BEN-
10 EFITS TO LATER TAXABLE YEARS.—

11 “(1) IN GENERAL.—For purposes of this title—

12 “(A) a plan or other arrangement shall not
13 fail to be treated as a cafeteria plan or flexible
14 spending or similar arrangement, and

15 “(B) no amount shall be required to be in-
16 cluded in gross income by reason of this section
17 or any other provision of this chapter,

18 solely because under such plan or other arrangement
19 any nontaxable benefit which is unused as of the
20 close of a taxable year may be carried forward to 1
21 or more succeeding taxable years.

22 “(2) LIMITATION.—Paragraph (1) shall not
23 apply to amounts carried from a plan to the extent
24 such amounts exceed \$500 (applied on an annual
25 basis). For purposes of this paragraph, all plans and

1 arrangements maintained by an employer or any re-
2 lated person shall be treated as 1 plan.

3 “(3) ALLOWANCE OF ROLLOVER.—

4 “(A) IN GENERAL.—Each flexible spending
5 or similar arrangement which permits a carry-
6 over under paragraph (1) of an amount of un-
7 used benefit shall provide that each participant
8 may elect, in lieu of a carryover of such
9 amount, to have such amount distributed to the
10 participant.

11 “(B) AMOUNTS NOT INCLUDED IN IN-
12 COME.—Any distribution under subparagraph
13 (A) shall not be included in gross income to the
14 extent that such amount is transferred in a
15 trustee-to-trustee transfer, or is contributed
16 within 60 days of the date of the distribution,
17 to—

18 “(i) an individual retirement plan,

19 “(ii) a qualified cash or deferred ar-
20 rangement described in section 401(k),

21 “(iii) a plan under which amounts are
22 contributed by an individual’s employer for
23 an annuity contract described in section
24 403(b),

1 “(iv) an eligible deferred compensa-
2 tion plan described in section 457,

3 “(v) a medical savings account (within
4 the meaning of section 220), or

5 “(vi) an education individual retire-
6 ment account (within the meaning of sec-
7 tion 530(b)).

8 Any amount rolled over under this subpara-
9 graph shall be treated as a rollover contribution
10 for the taxable year from which the unused
11 amount would otherwise be carried.

12 “(C) TREATMENT OF ROLLOVER.—Any
13 amount rolled over under subparagraph (B)
14 shall be treated as an eligible rollover under
15 section 219, 220, 401(k), 403(b), 457, or 530,
16 whichever is applicable, and shall not be taken
17 into account in applying any limitation (or par-
18 ticipation requirement) on contributions under
19 such section or any other provision of this chap-
20 ter for the taxable year of the rollover.

21 “(4) COST-OF-LIVING ADJUSTMENT.—In the
22 case of any taxable year beginning in a calendar
23 year after 1999, the \$500 amount under paragraph
24 (2) shall be adjusted at the same time and in the
25 same manner as under section 415(d)(2), except

1 that the base period taken into account shall be the
2 calendar quarter beginning October 1, 1998, and
3 any increase which is not a multiple of \$50 shall be
4 rounded to the next lowest multiple of \$50.”.

5 (b) EFFECTIVE DATE.—The amendments made by
6 this section shall apply to taxable years beginning after
7 December 31, 1998.

8 **TITLE IV—HEALTH CARE**

9 **LAWSUIT REFORM**

10 **Subtitle A—General Provisions**

11 **SEC. 401. FEDERAL REFORM OF HEALTH CARE LIABILITY**

12 **ACTIONS.**

13 (a) APPLICABILITY.—This title shall apply with re-
14 spect to any health care liability action brought in any
15 State or Federal court, except that this title shall not
16 apply to—

17 (1) an action for damages arising from a vac-
18 cine-related injury or death to the extent that title
19 XXI of the Public Health Service Act applies to the
20 action; or

21 (2) an action under the Employee Retirement
22 Income Security Act of 1974 (29 U.S.C. 1001 et
23 seq.).

24 (b) PREEMPTION.—This title shall preempt any State
25 law to the extent such law is inconsistent with the limita-

1 tions contained in this title. This title shall not preempt
2 any State law that provides for defenses or places limita-
3 tions on a person's liability in addition to those contained
4 in this title or otherwise imposes greater restrictions than
5 those provided in this title.

6 (c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE
7 OF LAW OR VENUE.—Nothing in subsection (b) shall be
8 construed to—

9 (1) waive or affect any defense of sovereign im-
10 munity asserted by any State under any provision of
11 law;

12 (2) waive or affect any defense of sovereign im-
13 munity asserted by the United States;

14 (3) affect the applicability of any provision of
15 the Foreign Sovereign Immunities Act of 1976;

16 (4) preempt State choice-of-law rules with re-
17 spect to claims brought by a foreign nation or a cit-
18 izen of a foreign nation; or

19 (5) affect the right of any court to transfer
20 venue or to apply the law of a foreign nation or to
21 dismiss a claim of a foreign nation or of a citizen
22 of a foreign nation on the ground of inconvenient
23 forum.

24 (d) AMOUNT IN CONTROVERSY.—In an action to
25 which this title applies and which is brought under section

1 1332 of title 28, United States Code, the amount of non-
2 economic damages or punitive damages, and attorneys'
3 fees or costs, shall not be included in determining whether
4 the matter in controversy exceeds the sum or value of
5 \$50,000.

6 (e) FEDERAL COURT JURISDICTION NOT ESTAB-
7 LISHED ON FEDERAL QUESTION GROUNDS.—Nothing in
8 this title shall be construed to establish any jurisdiction
9 in the district courts of the United States over health care
10 liability actions on the basis of section 1331 or 1337 of
11 title 28, United States Code.

12 **SEC. 402. DEFINITIONS.**

13 As used in this title:

14 (1) ACTUAL DAMAGES.—The term “actual dam-
15 ages” means damages awarded to pay for economic
16 loss.

17 (2) ALTERNATIVE DISPUTE RESOLUTION SYS-
18 TEM; ADR.—The term “alternative dispute resolution
19 system” or “ADR” means a system established
20 under Federal or State law that provides for the res-
21 olution of health care liability claims in a manner
22 other than through health care liability actions.

23 (3) CLAIMANT.—The term “claimant” means
24 any person who brings a health care liability action
25 and any person on whose behalf such an action is

1 brought. If such action is brought through or on be-
2 half of an estate, the term includes the claimant's
3 decedent. If such action is brought through or on be-
4 half of a minor or incompetent, the term includes
5 the claimant's legal guardian.

6 (4) CLEAR AND CONVINCING EVIDENCE.—The
7 term “clear and convincing evidence” is that meas-
8 ure or degree of proof that will produce in the mind
9 of the trier of fact a firm belief or conviction as to
10 the truth of the allegations sought to be established.
11 Such measure or degree of proof is more than that
12 required under preponderance of the evidence but
13 less than that required for proof beyond a reason-
14 able doubt.

15 (5) COLLATERAL SOURCE PAYMENTS.—The
16 term “collateral source payments” means any
17 amount paid or reasonably likely to be paid in the
18 future to or on behalf of a claimant, or any service,
19 product, or other benefit provided or reasonably like-
20 ly to be provided in the future to or on behalf of a
21 claimant, as a result of an injury or wrongful death,
22 pursuant to—

23 (A) any State or Federal health, sickness,
24 income-disability, accident or workers' com-
25 pensation Act;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(6) DRUG.—The term “drug” has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(7) ECONOMIC LOSS.—The term “economic loss” means any pecuniary loss resulting from injury (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities), to the extent recovery for such loss is allowed under applicable State law.

(8) HARM.—The term “harm” means any legally cognizable wrong or injury for which punitive damages may be imposed.

1 (9) HEALTH BENEFIT PLAN.—The term
2 “health benefit plan” means—

3 (A) a hospital or medical expense incurred
4 policy or certificate;

5 (B) a hospital or medical service plan con-
6 tract;

7 (C) a health maintenance subscriber con-
8 tract; or

9 (D) a Medicare+Choice plan (offered
10 under part C of title XVIII of the Social Secu-
11 rity Act),

12 that provides benefits with respect to health care
13 services.

14 (10) HEALTH CARE LIABILITY ACTION.—The
15 term “health care liability action” means a civil ac-
16 tion brought in a State or Federal court against—

17 (A) a health care provider;

18 (B) an entity which is obligated to provide
19 or pay for health benefits under any health ben-
20 efit plan (including any person or entity acting
21 under a contract or arrangement to provide or
22 administer any health benefit); or

23 (C) the manufacturer, distributor, supplier,
24 marketer, promoter, or seller of a medical prod-
25 uct,

1 in which the claimant alleges a claim (including third
2 party claims, cross claims, counter claims, or contribution
3 claims) based upon the provision of (or the failure to pro-
4 vide or pay for) health care services or the use of a medical
5 product, regardless of the theory of liability on which the
6 claim is based or the number of plaintiffs, defendants, or
7 causes of action.

8 (11) HEALTH CARE LIABILITY CLAIM.—The
9 term “health care liability claim” means a claim in
10 which the claimant alleges that injury was caused by
11 the provision of (or the failure to provide) health
12 care services.

13 (12) HEALTH CARE PROVIDER.—The term
14 “health care provider” means any person that is en-
15 gaged in the delivery of health care services in a
16 State and that is required by the laws or regulations
17 of the State to be licensed or certified by the State
18 to engage in the delivery of such services in the
19 State.

20 (13) HEALTH CARE SERVICE.—The term
21 “health care service” means any service eligible for
22 payment under a health benefit plan, including serv-
23 ices related to the delivery or administration of such
24 service.

1 (14) MEDICAL DEVICE.—The term “medical de-
2 vice” has the meaning given such term in section
3 201(h) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 321(h)).

5 (15) NON-ECONOMIC DAMAGES.—The term
6 “non-economic damages” means damages paid to an
7 individual for pain and suffering, inconvenience,
8 emotional distress, mental anguish, loss of consor-
9 tium, injury to reputation, humiliation, and other
10 nonpecuniary losses.

11 (16) PERSON.—The term “person” means any
12 individual, corporation, company, association, firm,
13 partnership, society, joint stock company, or any
14 other entity, including any governmental entity.

15 (17) PRODUCT SELLER.—

16 (A) IN GENERAL.—Subject to subpara-
17 graph (B), the term “product seller” means a
18 person who, in the course of a business con-
19 ducted for that purpose—

20 (i) sells, distributes, rents, leases, pre-
21 pares, blends, packages, labels, or is other-
22 wise involved in placing, a product in the
23 stream of commerce; or

24 (ii) installs, repairs, or maintains the
25 harm-causing aspect of a product.

(B) EXCLUSION.—Such term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(18) PUNITIVE DAMAGES.—The term “punitive damages” means damages awarded against any person not to compensate for actual injury suffered, but to punish or deter such person or others from engaging in similar behavior in the future.

(19) STATE.—The term “State” means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa,

1 the Northern Mariana Islands, and any other terri-
2 tory or possession of the United States.

3 **SEC. 403. EFFECTIVE DATE.**

4 This title will apply to—

5 (1) any health care liability action brought in a
6 Federal or State court; and

7 (2) any health care liability claim subject to an
8 alternative dispute resolution system,

9 that is initiated on or after the date of enactment of this
10 title, except that any health care liability claim or action
11 arising from an injury occurring before the date of enact-
12 ment of this title shall be governed by the applicable stat-
13 ute of limitations provisions in effect at the time the injury
14 occurred.

15 **Subtitle B—Uniform Standards for**
16 **Health Care Liability Actions**

17 **SEC. 411. STATUTE OF LIMITATIONS.**

18 A health care liability action may not be brought
19 after the expiration of the 2-year period that begins on
20 the date on which the alleged injury that is the subject
21 of the action was discovered or should reasonably have
22 been discovered, but in no case after the expiration of the
23 5-year period that begins on the date the alleged injury
24 occurred.

1 **SEC. 412. CALCULATION AND PAYMENT OF DAMAGES.**

2 (a) **TREATMENT OF NON-ECONOMIC DAMAGES.—**

3 (1) **LIMITATION ON NON-ECONOMIC DAM-**
4 **AGES.—**The total amount of non-economic damages
5 that may be awarded to a claimant for losses result-
6 ing from the injury which is the subject of a health
7 care liability action may not exceed \$250,000, re-
8 gardless of the number of parties against whom the
9 action is brought or the number of actions brought
10 with respect to the injury. The limitation under this
11 paragraph shall not apply to an action for damages
12 based solely on intentional denial of medical treat-
13 ment necessary to preserve a patient's life that the
14 patient is otherwise qualified to receive, against the
15 wishes of a patient, or if the patient is incompetent,
16 against the wishes of the patient's guardian, on the
17 basis of the patient's present or predicated age, dis-
18 ability, degree of medical dependency, or quality of
19 life.

20 (2) **LIMIT.—**If, after the date of the enactment
21 of this Act, a State enacts a law which prescribes
22 the amount of non-economic damages which may be
23 awarded in a health care liability action which is dif-
24 ferent from the amount prescribed by section
25 412(a)(1), the State amount shall apply in lieu of
26 the amount prescribed by such section. If, after the

1 date of the enactment of this Act, a State enacts
2 a law which limits the amount of recovery in a
3 health care liability action without delineating be-
4 tween economic and non-economic damages, the
5 State amount shall apply in lieu of the amount pre-
6 scribed by such section.

7 (3) JOINT AND SEVERAL LIABILITY.—In any
8 health care liability action brought in State or Fed-
9 eral court, a defendant shall be liable only for the
10 amount of non-economic damages attributable to
11 such defendant in direct proportion to such defend-
12 ant's share of fault or responsibility for the claim-
13 ant's actual damages, as determined by the trier of
14 fact. In all such cases, the liability of a defendant
15 for non-economic damages shall be several and not
16 joint and a separate judgment shall be rendered
17 against each defendant for the amount allocated to
18 such defendant.

19 (b) TREATMENT OF PUNITIVE DAMAGES.—

20 (1) GENERAL RULE.—Punitive damages may,
21 to the extent permitted by applicable State law, be
22 awarded in any health care liability action for harm
23 in any Federal or State court against a defendant if
24 the claimant establishes by clear and convincing evi-

dence that the harm suffered was the result of conduct—

(A) specifically intended to cause harm; or

(B) conduct manifesting a conscious, flagrant indifference to the rights or safety of others.

(2) APPLICABILITY.—This subsection shall apply to any health care liability action brought in any Federal or State court on any theory where punitive damages are sought. This subsection does not create a cause of action for punitive damages.

(3) LIMITATION ON PUNITIVE DAMAGES.—The total amount of punitive damages that may be awarded to a claimant for losses resulting from the injury which is the subject of a health care liability action may not exceed the greater of—

(A) 2 times the amount of economic damages, or

(B) \$250,000,

regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury. This subsection does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages.

1 (4) BIFURCATION.—At the request of any
2 party, the trier of fact shall consider in a separate
3 proceeding whether punitive damages are to be
4 awarded and the amount of such award. If a sepa-
5 rate proceeding is requested, evidence relevant only
6 to the claim of punitive damages, as determined by
7 applicable State law, shall be inadmissible in any
8 proceeding to determine whether actual damages are
9 to be awarded.

10 (5) DRUGS AND DEVICES.—

11 (A) IN GENERAL.—

12 (i) PUNITIVE DAMAGES.—Punitive
13 damages shall not be awarded against a
14 manufacturer or product seller of a drug
15 or medical device which caused the claim-
16 ant's harm where—

17 (I) such drug or device was sub-
18 ject to premarket approval by the
19 Food and Drug Administration with
20 respect to the safety of the formula-
21 tion or performance of the aspect of
22 such drug or device which caused the
23 claimant's harm, or the adequacy of
24 the packaging or labeling of such drug
25 or device which caused the harm, and

1 such drug, device, packaging, or label-
2 ing was approved by the Food and
3 Drug Administration; or

4 (II) the drug is generally recog-
5 nized as safe and effective pursuant to
6 conditions established by the Food
7 and Drug Administration and applica-
8 ble regulations, including packaging
9 and labeling regulations.

10 (ii) APPLICATION.—Clause (i) shall
11 not apply in any case in which the defend-
12 ant, before or after premarket approval of
13 a drug or device—

14 (I) intentionally and wrongfully
15 withheld from or misrepresented to
16 the Food and Drug Administration in-
17 formation concerning such drug or de-
18 vice required to be submitted under
19 the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 301 et seq.) or
21 section 351 of the Public Health Serv-
22 ice Act (42 U.S.C. 262) that is mate-
23 rial and relevant to the harm suffered
24 by the claimant; or

1 (II) made an illegal payment to
2 an official or employee of the Food
3 and Drug Administration for the pur-
4 pose of securing or maintaining ap-
5 proval of such drug or device.

6 (B) PACKAGING.—In a health care liability
7 action for harm which is alleged to relate to the
8 adequacy of the packaging or labeling of a drug
9 which is required to have tamper-resistant
10 packaging under regulations of the Secretary of
11 Health and Human Services (including labeling
12 regulations related to such packaging), the
13 manufacturer or product seller of the drug shall
14 not be held liable for punitive damages unless
15 such packaging or labeling is found by the court
16 by clear and convincing evidence to be substan-
17 tially out of compliance with such regulations.

18 (c) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

19 (1) GENERAL RULE.—In any health care liabil-
20 ity action in which the damages awarded for future
21 economic and non-economic loss exceeds \$50,000, a
22 person shall not be required to pay such damages in
23 a single, lump-sum payment, but shall be permitted
24 to make such payments periodically based on when

1 the damages are likely to occur, as such payments
2 are determined by the court.

3 (2) FINALITY OF JUDGMENT.—The judgment
4 of the court awarding periodic payments under this
5 subsection may not, in the absence of fraud, be re-
6 opened at any time to contest, amend, or modify the
7 schedule or amount of the payments.

8 (3) LUMP-SUM SETTLEMENTS.—This sub-
9 section shall not be construed to preclude a settle-
10 ment providing for a single, lump-sum payment.

11 (d) TREATMENT OF COLLATERAL SOURCE PAY-
12 MENTS.—

13 (1) INTRODUCTION INTO EVIDENCE.—In any
14 health care liability action, any defendant may intro-
15 duce evidence of collateral source payments. If any
16 defendant elects to introduce such evidence, the
17 claimant may introduce evidence of any amount paid
18 or contributed or reasonably likely to be paid or con-
19 tributed in the future by or on behalf of the claim-
20 ant to secure the right to such collateral source pay-
21 ments.

22 (2) NO SUBROGATION.—No provider of collat-
23 eral source payments shall recover any amount
24 against the claimant or receive any lien or credit
25 against the claimant's recovery or be equitably or le-

1 gally subrogated to the right of the claimant in a
2 health care liability action.

3 (3) APPLICATION TO SETTLEMENTS.—This sub-
4 section shall apply to an action that is settled as well
5 as an action that is resolved by a fact finder.

6 **SEC. 413. LIMITATIONS ON CONTINGENT FEES.**

7 (a) IN GENERAL.—The total of all contingent fees
8 for representing all claimants in a health care liability
9 claim or action shall not exceed the following limits:

10 (1) 40 percent of the first \$500,000 recovered
11 by the claimant.

12 (2) 33 1/3 percent of the next \$50,000 recov-
13 ered by the claimant.

14 (3) 25 percent of the next \$50,000 recovered by
15 the claimant.

16 (4) 15 percent of any amount by which the re-
17 covery by the claimant exceeds \$600,000.

18 (b) APPLICABILITY.—The limitations prescribed by
19 subsection (a) shall apply whether the recovery is by judg-
20 ment, settlement, mediation, arbitration, or any other
21 form of ADR. A court acting in a health care liability
22 claim or action involving a minor or incompetent person
23 retains the authority to authorize or approve a fee that
24 is less than the maximum permitted under subsection (a).

25 (c) DEFINITIONS.—For purposes of this section:

1 (1) CONTINGENT FEE.—The term “contingent
2 fee” includes all compensation to any person which
3 is payable only if a recovery is effected on behalf of
4 one or more claimants.

5 (2) RECOVERY.—The term “recovery” means
6 the net sum recovered after deducting any disburse-
7 ments or costs incurred in connection with prosecu-
8 tion or settlement of the claim, including all costs
9 paid or advanced by any person. Costs of health care
10 incurred by the plaintiff and the attorney’s office
11 overhead costs or charges for legal services are not
12 deductible disbursements of costs for such purpose.

13 **SEC. 413. ALTERNATIVE DISPUTE RESOLUTION.**

14 Any ADR used to resolve a health care liability action
15 or claim shall contain provisions relating to statute of limi-
16 tations, non-economic damages, joint and several liability,
17 punitive damages, collateral source rule, and periodic pay-
18 ments which are consistent with the provisions relating to
19 such matters in this title.

20 **SEC. 414. REPORTING ON FRAUD AND ABUSE ENFORCE-**
21 **MENT ACTIVITIES.**

22 The General Accounting Office shall—

23 (1) monitor—

24 (A) the compliance of the Department of
25 Justice and all United States Attorneys—with



1 the guideline entitled “Guidance on the Use of
2 the False Claims Act in Civil Health Care Mat-
3 ters” issued by the Department on June 3,
4 1998, including any revisions to that guideline;
5 and

6 (B) the compliance of the Office of the In-
7 spector General of the Department of Health
8 and Human Services with the protocols and
9 guidelines entitled “National Project Proto-
10 cols—Best Practice Guidelines” issued by the
11 Inspector General on June 3, 1998, including
12 any revisions to such protocols and guidelines;
13 and .

14 (2) submit a report on such compliance to the
15 Committee on Commerce, the Committee on the Ju-
16 diciary, and the Committee on Ways and Means of
17 the House of Representatives and the Committee on
18 the Judiciary and the Committee on Finance of the
19 Senate not later than February 1, 2000, and every
20 year thereafter for a period of 4 years ending Feb-
21 ruary 1, 2003.

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